

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

AURED Reference	NA
Barwon Health Reference	13/14
Project Title	Personalised Health Care Proof of Concept Pilot Study
Protocol Reference	
Principal Researcher	Robyn Hayles
Research Team	Dr Peter Martin, A/Prof Mark Kotowicz, Dr Chris Steinfort, Mr Julian Toscano, Dr Stephen Lane, Ms Rebecca Eastgate, Ms Josephine Stevens

was considered by the Human Research Ethics Committee at the meeting of **10/04/13** and having fulfilled the requirements of the National Statement on Ethical Conduct in Human Research (2007), was **APPROVED** on **[date]**.

Approved Documents:

- *Protocol VERSION 1.4 - 02/09/2013*
- *Participant Information and Consent Form FINAL dated 03/12/13*
- *Barwon Health Participant Invite Letter FINAL dated 08/09/13 2013*
- *Amendment dated 24.11.2013*

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Office for Research, via amendment or report, of:

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Any serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in their role, or any other change in research personnel involved in the project;
- A delay of more than 12 months in the commencement of the project;
- Annual progress reports on the progress of the project and at the conclusion of the project. Failure to report as required may result in suspension of your approval to proceed with the project and;
- If applicable, please provide the clinical trial registration number.



This approval covers the project as described in the application (including any modifications made prior to approval).

SPECIAL CONDITIONS

The site/s to which this approval pertains includes:

- *Barwon Health*

Please note that template forms for reporting changes to the project and annual/final reports may be obtained from the Department of Health website:

<http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm>


All research subject to the Barwon Health Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007). Barwon Health may conduct an audit at any time.

The Barwon Health Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

On behalf of the Committee, best wishes for your project.

Please quote the project number and title in all correspondence.

Yours sincerely



SIMON FRENCH

Chair

Human Research Ethics Committee

Site Specific Assessment (SSA)

SSA authorisation is required at all sites participating in this study. This letter also indicates that site specific assessment has been authorised at Barwon Health.

Yours sincerely



BERNICE DAVIES

Research Governance Officer, Barwon Health

Office for Research

Chair's

Human Research Ethics Committee
Mr Simon French, LLB

Research Review Committee Chair
Dr Giuliana Fuscaldo

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