

ETHICS COMMITTEE CERTIFICATE OF APPROVAL



Barwon Health Reference	17/15
Project Title	Can we reduce tobacco smoking using N-acetylcysteine as a cessation treatment?
Protocol Reference	NAC SMOKING
Principal Researcher	A/Prof Seetal Dodd
Research Team	Prof Michael Berk, Dr Olivia Dean

The above project was considered by the Human Research Ethics Committee at the meeting of 12 April 2017 and having fulfilled the requirements of the National Statement on Ethical Conduct in Human Research (2007), was approved on 19 June 2017.

The documents reviewed and approved are:

NEAF
PICF Version 2 dated 30/05/2017
Protocol Version 2 dated 30/05/2017
Study Termination Form Version 1 dated 30/05/2017

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 Research Ethics, Governance & Integrity (REGI) Unit, 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).

Please quote the Barwon Health reference number and title in all future correspondence.

Special Conditions

The site/s to which this approval pertains includes:

- *Barwon Health*

Templates 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 HREC 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 HREC 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.

Yours sincerely



Mr Richard Larsen
Research Ethics Officer
Research Ethics, Governance & Integrity (REGI) Unit
Barwon Health

on behalf of

Mr 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



Ms Lisa Fry
Research Governance Officer
Research Ethics, Governance & Integrity (REGI) Unit
Barwon Health

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Reminder: Barwon Health and Deakin University Research Week (13 – 17 November 2017)

Barwon Health and Deakin University researchers are encouraged to share their research findings with the community during Research Week and are welcome to join this year's Poster Competition. Details are available via the link below:

<http://www.barwonhealth.org.au/research-week>

