



Human Research Ethics Committee (HREC)
The University of New South Wales
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E: humanethics@unsw.edu.au

W: <https://research.unsw.edu.au/human-research-ethics-home>

09-Jan-2017

Dear Professor Michael Farrell,

Project Title	A non-inferiority trial of cytisine versus varenicline for smoking cessation
HC No	HC16888
Re	Notification of Ethics Approval
Approval Period	09-Jan-2017 - 08-Jan-2022

Thank you for submitting the above research project to the **HREC Executive** for ethical review. This project was considered by the **HREC Executive** at its meeting on 05-Jan-2017.

I am pleased to advise you that the **HREC Executive** has granted ethical approval of this research project, subject to the following conditions being met:

Conditions of Approval Specific to Project:

N/A

Conditions of Approval - All Projects:

- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will notify the **HREC Executive** of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the **HREC Executive**. These instructions can be found at <https://research.unsw.edu.au/research-ethics-and-compliance-support-recs>.
- The Chief Investigator will submit any necessary reports related to the safety of research participants in accordance with **HREC Executive** policy and procedures. These instructions can be found at <https://research.unsw.edu.au/research-ethics-and-compliance-support-recs>.
- The Chief Investigator will report to the **HREC Executive** annually in the specified format and notify the HREC Executive when the project is completed at all sites.
- The Chief Investigator will notify the **HREC Executive** if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Chief Investigator will notify the **HREC Executive** of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <https://research.unsw.edu.au>

[/research-ethics-and-compliance-support-recs](https://research.unsw.edu.au/research-ethics-and-compliance-support-recs).

- The Chief Investigator will notify the **HREC Executive** of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.

A copy of this ethical approval letter must be submitted to all Investigators and sites prior to commencing the project.

The **HREC Executive** Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <https://research.unsw.edu.au/research-ethics-and-compliance-support-recs>.

If you would like any assistance, or further information, please contact the ethics office on:

P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007

E: humanethics@unsw.edu.au

The **HREC Executive** wishes you continued success in your research.

Kind Regards



A/Prof John Hunt

HREC Presiding Chairperson

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.