

University Human Research Ethics Committee (UHREC)

HUMAN RESEARCH ETHICS APPROVAL CERTIFICATE NHMRC Registered Committee Number EC00171

Date of Issue: 11/4/17 (supersedes all previously issued certificates)

Dear Prof Danielle Gallegos

This approval certificate serves as your written notice that the proposal has met the requirements of the *National Statement on Ethical Conduct in Human Research* and has been approved on that basis. You are therefore authorised to commence activities as outlined in your application, subject to any specific and standard conditions detailed in this document.

Project Details

Category of Approval: Committee

Approved From: 30/11/2016 Approved Until: 30/11/2019 (subject to annual reports)

Approval Number: 1600000959

Project Title: The effectiveness of individualised dietary counselling in the treatment of malnutrition ir

Vietnamese COPD Outpatients: A randomised controlled trial

Investigator Details

Chief Investigator: Prof Danielle Gallegos

Other Staff/Students:

Investigator Name Type Role

Mrs Thanh Ha Nguyen Student Doctoral (Research)

Dr Peter Collins Internal QUT Associate Supervisor

Conditions of Approval

Specific Conditions of Approval:

No special conditions placed on approval by the UHREC. Standard conditions apply.

Standard Conditions of Approval:

- 1. Conduct the project in accordance with the principles of the NHMRC National Statement on Ethical Conduct in Human Research, 2007 and any additional specific conditions defined by the UHREC, any associated NHMRC guidelines and regulations, and the provisions of any legislation which is relevant to the project;
- 2. Obtain UHREC approval for any proposed variation to the project **prior** to implementation (note that major changes may require a different level of review and/or submission of a new application);
- 3. Obtain any additional approvals or authorisations as required (e.g. from other ethics committees, collaborating institutions, supporting organisations);
- 4. Maintain research records and data in accordance with MoPP D/2.8 Management of research data.
- 5. Respond promptly to the requests and instructions of UHREC;
- 6. Declare all actual, perceived or potential conflicts of interest (NS 5.4);
- 7. Immediately advise the Office of Research Ethics and Integrity (OREI) of any concerns, complaints or adverse events including (NS 5.5.3):
 - o if any unforeseen development or events occur that might affect the continued ethical acceptability of the project;
 - if any complaints are made, or expressions of concern are raised, in relation to the project;
 - o if the project needs to be suspended or modified because the risks to participants now outweigh the benefits
 - o if a participant can no longer be involved because the research may harm them.
- 8. Report on the progress of the project at least annually, or at intervals determined by UHREC (NS 5.5.5);
- 9. Participate in project monitoring activities in accordance with MoPP D/2.4 Monitoring of research approved by a University Review Body, if required.

If any details within this Approval Certificate are incorrect please advise the Research Ethics Unit within 10 days of receipt of this certificate.

End of Document

RM Report No. E801 Version 4.7 Page 1 of 1