HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Professor Peter Howe**
Cc Co-investigators / Research Students:	**Doctor Rachel Wong** **Mr Hamish Evans**
Re Protocol:	**Assisting post-menopausal women towards healthy ageing - can resveratrol enhance mood, physical function and cerebrovascular function and counteract cognitive decline?**
Date:	**13-Mar-2015**
Reference No:	**H-2015-0002**
Date of Initial Approval:	**13-Mar-2015**

Thank you for your **Response to Conditional Approval (minor amendments)** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **Expedited** review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is **Approved** effective **13-Mar-2015**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2015-0002**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

Note - This approval extends to the following variations to the protocol:

1. Addition of Hamish Evans (Honours student) to the research team - research data will contribute to Mr Evans' Honours Thesis;
2. Inclusion of the HMRI logo in the Recruitment Flyer;
3. Amend the contact person *from* Dr Rachel Wong *to* Mr Hamish Evans;
4. Amend the intervention duration *from* 17 week *to* 14 weeks;
5. Remove the intermediate assessment at the 2-month time point (reducing clinic visits from 3 to 2); and
6. Add a follow-up telephone call to participants between weeks 6 and 8 of the intervention to check safety and compliance with treatment.

- Participant Information Statement (v1.1, dated 10-Mar-2015);
- Consent Form (v1.1, dated 10-Mar-2015);
- Clinical Research Protocol: Assisting Post-Menopausal Women Towards Healthy Ageing - Can Resveratrol Enhance Mood, Physical Function and Cerebrovascular Function and Counteract Cognitive Decline? (version dated 10-Mar-2015);

*****Please note the following:**

1. Reimbursement.
The current wording in the PIS regarding reimbursement implies that people who complete the Health, Diet & Lifestyle Questionnaire (as part of screening) will also be eligible to receive $10 reimbursement, even if they are screened out at this point. If this is not the intent, the wording should be amended to reflect that payment is only made to participants/potential participants who attend a session at the University (this was the intent of our original comment). If the document is amended, please submit a copy via email to ruth.gibbins@newcastle.edu.au.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at https://rims.newcastle.edu.au/login.asp) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at https://rims.newcastle.edu.au/login.asp). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

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RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
Hunter Medical Research Institute/Project Grant(**)	Assisting post-menopausal women towards healthy ageing - can resveratrol enhance mood and counteract cognitive decline?	Howe, Peter	G1401413