



University Human Research Ethics Committee  
**HUMAN ETHICS APPROVAL CERTIFICATE**  
 NHMRC Registered Committee Number EC00171

**Date of Issue:** 16/6/14 (supersedes all previously issued certificates)

Dear Prof Ann Bonner

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 proposal application, subject to any specific and standard conditions detailed in this document.

**Project Details**

**Category of Approval:** Human Negligible-Low Risk  
**Approved From:** 16/06/2014 **Approved Until:** 16/06/2016 (subject to annual reports)  
**Approval Number:** 1400000374  
**Project Title:** A self-management program for people with heart failure in Hanoi, Vietnam: A randomised controlled trial

**Investigator Details**

**Chief Investigator:** Prof Ann Bonner

**Other Staff/Students:**

Investigator Name	Type	Role
Dr Joanne Ramsbotham	Internal	Ethics - QUT Associate Supervisor
Ms Thi Thuy Ha Dinh	Student	Ethics- Student- Research- Doctoral
Prof Robyn Clark	External	Other

**Conditions of Approval**

**Specific Conditions of Approval:**

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

**Standard Conditions of Approval:**

The University's standard conditions of approval require the research team to:

1. Conduct the project in accordance with University policy, NHMRC / AVCC guidelines and regulations, and the provisions of any relevant State / Territory or Commonwealth regulations or legislation;
2. Respond to the requests and instructions of the University Human Research Ethics Committee (UHREC);
3. Advise the Research Ethics Coordinator immediately if any complaints are made, or expressions of concern are raised, in relation to the project;
4. Suspend or modify the project if the risks to participants are found to be disproportionate to the benefits, and immediately advise the Research Ethics Coordinator of this action;
5. Stop any involvement of any participant if continuation of the research may be harmful to that person, and immediately advise the Research Ethics Coordinator of this action;
6. Advise the Research Ethics Coordinator of any unforeseen development or events that might affect the continued ethical acceptability of the project;
7. Report on the progress of the approved project at least annually, or at intervals determined by the Committee;
8. (Where the research is publicly or privately funded) publish the results of the project in such a way to permit



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scrutiny and contribute to public knowledge; and

9. Ensure that the results of the research are made available to the participants.

**Modifying your Ethical Clearance:**

Requests for variations must be made via submission of a Request for Variation to Existing Clearance Form (<http://www.research.qut.edu.au/ethics/forms/hum/var/var.jsp>) to the Research Ethics Coordinator. Minor changes will be assessed on a case by case basis.

It generally takes 7-14 days to process and notify the Chief Investigator of the outcome of a request for a variation.

Major changes, depending upon the nature of your request, may require submission of a new application.

**Audits:**

All active ethical clearances are subject to random audit by the UHREC, which will include the review of the signed consent forms for participants, whether any modifications / variations to the project have been approved, and the data storage arrangements.

Further information regarding your ongoing obligations regarding human based research can be found via the Research Ethics website <http://www.research.qut.edu.au/ethics/> or by contacting the Research Ethics Coordinator on 07 3138 2091 or [ethicscontact@qut.edu.au](mailto:ethicscontact@qut.edu.au)

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

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