UNIVERSITY OF WOLLONGONG
HUMAN RESEARCH ETHICS COMMITTEE
PROGRESS / RENEWAL REPORT

HREC Approval No: HE09/002

Expiry Date: February 2010

Project Title: MACS325

Chief Investigator: Brian Martin and Chris Barker

General Notes and Conditions

The National Statement on Ethical Conduct in Research Involving Humans requires institutions to monitor research projects involving human participants to ensure that they are conducted ethically and in compliance with the HREC approval for that project, including any conditions placed on that approval.

For the most part, the monitoring requirement will be satisfied by the chief investigator:
- notifying the HREC immediately of any serious or unexpected adverse effects on participants;
- notifying the HREC of any proposed changes to the protocol or procedures to be used in the research;
- notifying the HREC of unforeseen events that might affect continued ethical acceptability of the project;
- providing the HREC with an annual report on the project; and
- providing the HREC with a report at the completion of the project.

In special circumstances the HREC may ask for more frequent reports and may require additional monitoring if it considers this necessary to ensure that the project continues to conform to ethical standards. While the principal objective of monitoring is to ensure that the rights and interests of human participants are not jeopardised, it is also concerned to foster responsible research.

This form is to be used for:
- Reports of serious or unexpected adverse effects on participants;
- Reports of proposed changes to protocols/projects;
- Reports of unforeseen events that might affect ethical acceptability of projects;
- Annual reports on approved research project;
- Request for renewal of approval; and
- Final reports on projects at the completion of research

Please complete this report referring back where necessary to your application for ethics clearance, which is the approved protocol, and any special conditions imposed by the HREC. If there is insufficient space to answer any question please attach a separate sheet. If a question does not apply to your research please write "N/A" or "not applicable" in the space provided.

Please return your completed report within 14 days to the Human Research Ethics Officer, Research Office, University of Wollongong, Wollongong NSW 2522 (Ph: 4221 4457; Fax: 4221 4338).

TO BE COMPLETED FOR ALL RESEARCH PROJECTS INVOLVING HUMAN PARTICIPANTS.

Please tick where appropriate.

1. Purpose of this report (tick as many as are appropriate):

_____Report of serious or unexpected adverse effects on participants
_____Report of proposed changes to the protocol/project
_____Report of unforeseen events that might affect ethical acceptability of the project
_____Annual report on approved research project
x____Request for renewal of approval
_____Final report on project

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2. Status of Research Project

_____Completed (date)_____

_____In progress. Anticipated completion date of Research Project_____

x____Renewal of approval requested until (date) July 2010_____ [Approval was given for the MACS325 class in 2009. We request it, under the same conditions, for the MACS325 class in autumn session 2010. The same activities will be carried out, by a different cohort of students.]

_____Commenced but abandoned on (date) _____
(please give below brief reasons why the project was abandoned, then sign and return this report.)

_____

3. Report on ethical aspects of project to date (or outcome in the case of completed research). Please detail method of contact with subjects, number of subjects involved, and the nature of their involvement in the research. Please comment on whether the research has complied with the approved protocol and any conditions of that approval from the HREC.

The students in MACS325 in 2009 interviewed various members of the community about happiness. About 80 subjects were involved. The research complied with the approved protocol.

4. In the conduct of this project have there been any variations to the approved protocol/project in respect of:

* Investigators — No

* Duration of Project (e.g. 1 year, 3 years) — Yes

* Research procedures (e.g. study design, sample size, source & method of recruitment, information & consent forms) — No

* Participant care & feedback — No

If you have answered YES to any part of this question:

* Has the HREC been previously notified of this event? — No

∑ Please provide brief details of the reasons for variations and how you will accommodate any problems they may pose for your research.

We would like to have students in this year's MACS325 class carry out interviews, like last year's students. This constitutes an extension of the project's duration.

∑ For Multicentre research, please provide a list of the Protocol Amendment numbers relevant to the research and a summary of the amendments for the year to date.

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5. Are any variations to the approved protocol/project proposed? If so, please detail below, noting that they must be approved by the HREC (attach an extra sheet if needed).

no

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6. Since your project commenced, how many participants have "dropped out"/withdrawn their consent?

0_____

Briefly list the reasons (if known) for participants dropping out/withdrawing from the project.

7. To the best of your knowledge, have any participants encountered adverse effects while participating in your research project? (e.g. side-effects of drugs or procedures, or other phenomena)

No

If YES: Number of participants involved _____

Briefly list adverse effects (attach and extra page if necessary).

For Multicentre research please attach a list and summary of Serious Adverse Event reports
(for Australia only) relevant to this research for the year to date.

Were all these effects anticipated in the Consent documents	Yes	No
Have these adverse effects been previously reported to the HREC?	Yes	No

What other action has been taken in response to these adverse effects?

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8. Have there been any other unforeseen incidents or complaints about the research that might affect the continued ethical acceptability of the project? (e.g. reactions to questionnaires or psychological tests)

No

If YES: Number of participants involved _____

Briefly list the incidents or complaints.

Have these events been previously reported to the HREC? Yes No

What other action has been taken in response to these incidents or complaints?

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9. Please comment on the methods used to store research data and any other personal information associated with this research

In a locked filing cabinet in the offices of Professor Brian Martin and A/Professor Chris Barker, Faculty of Arts

Have you encountered any problems associated with security and storage of data?
(All primary data must be retained for a period of at least five years to conform with the University's Code of Practice- Research.) No

If YES, give details.

10. Is your research project a CTN* or CTX* drug trial? No

*CTN = Clinical Trial Notification: CTX = Clinical Trial Exemption

If YES:

Have unused supplies of the trial drug been collected form participants?

Yes No Not applicable

Please attach one copy of the current information and consent package for this trial.

COMMENTS: Comments from you on ethical aspects relating to your research are very welcome.

DECLARATION:

I certify that the information provided by me in this Progress Report is an accurate account of the conduct of the above research project for which I am responsible and a copy of the Consent Form and Information Sheet used for this project is attached.

Signed (Chief Investigator)_____

Date _____

If Student is Chief Investigator, then Supervisor's signature is also required.

Supervisor_____(Name- Please Print)_____

Unit/ Faculty_____

Date _____

ALL REPORTS MUST BE SIGNED BY THE HEAD OF DEPARTMENT/UNIT
(This person must not be a member of the research team).

Position_____

Name_____

Signature_____

Date_____