

**CARDIOVASCULAR AND MENTAL HEALTH BENEFITS OF SOY CONSUMPTION:
ROLE OF SOY ISOFLAVONES**

Alicia A Thorp

B Med Pharm Biotech (Hons)

A thesis submitted for the degree of Doctor of Philosophy

Discipline of Physiology

University of Adelaide

South Australia

May 2008

APPENDICES

APPENDIX 1- Ethics Approval for Interventions

Alicia Thorp

From: Mizuno Oyuki on behalf of Vicki Allen
Sent: Thursday, 3 June 2004 10:16 AM
To: Alicia Thorp
Cc: Peter Howe; Karen Murphy; Jon Buckley; Helen Bagnell
Subject: Ethics Protocol P075/04 "Development and nutritional evaluation of novel foods based on a unique combination of soy and dairy products"
Attachments: Conditions.March 2004.doc

Dear Alicia,

Re: Ethics Protocol **P075/04 "Development and nutritional evaluation of novel foods based on a unique combination of soy and dairy products"**.

Thank you for providing the amendments and/or additional information requested by the Human Research Ethics Committee (letter dated 3 May 2004).

I am pleased to advise that your protocol has been approved. However, please make the further change to the Information Sheet: i.e. replace "Council" with "Committee" in the reference to the Human Research Ethics Committee in the last paragraph. I also remind you that it is your responsibility to ensure that the research is covered by the University's insurance policy.

Please regard this email as formal notification of approval.

Ethics approval is always made on the basis of a number of conditions detailed in the attachment; it is important that you are familiar with, and abide by, these conditions. It is also essential that you conduct all research according to UniSA guidelines, which can be found at <http://www.unisa.edu.au/orc/ethics/index.htm>.

Best wishes for your research.

Regards, Vicki

Vicki Allen
Ethics Officer
Research Services
University of South Australia
Mawson Lakes Campus
Mawson Lakes Boulevard
Mawson Lakes SA 5095
Telephone: + 61 8 8302 3118
Fax: +61 8 8302 3921
Email: vicki.allen@unisa.edu.au

RE: Ethics protocol P075/04 - extension to ethics approval

Subject: RE: Ethics protocol P075/04 - extension to ethics approval
From: Vicki Allen <Vicki.Allen@unisa.edu.au>
Date: Tue, 05 Apr 2005 11:30:54 +0930
To: peter howe <peter.howe@adelaide.edu.au>
CC: Alicia Thorp <alicia.thorp@unisa.edu.au>, Alison Morris <alison.morris@adelaide.edu.au>, Jon Buckley <Jon.Buckley@unisa.edu.au>

Dear Peter

Re: Ethics protocol P075/04 "Development and nutritional evaluation of novel foods based on a unique combination of soy diary products".

Thank you for your request for extension of ethics approval.

I am pleased to advise that your request to extend ethics approval until 31 December 2005 has been granted. I hope that you are able to recruit the additional participants required for your study and am pleased to learn that the data collected so far indicates there are significant benefits to the soy diet.

Regards, Vicki

Vicki Allen
Ethics Officer
Research Services
University of South Australia
Mawson Lakes Campus
Mawson Lakes Boulevard
Mawson Lakes SA 5095
Telephone: +61 8 8302 3118
Fax: +61 8 83023921
Email: vicki.allen@unisa.edu.au
CRIS Provider No. 00121B

-----Original Message-----

From: peter howe [mailto:peter.howe@adelaide.edu.au]
Sent: Monday, April 04, 2005 2:15 PM
To: Vicki Allen
Cc: Alicia Thorp; Alison Morris; Jon Buckley
Subject: ethics extension request attached

--

Prof. Peter Howe
Professorial Research Fellow in Nutritional Physiology, University of Adelaide and University of South Australia

School of Molecular & Biomedical Science
University of Adelaide
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APPLICATION FOR EXTENSION

*Please send the completed form to the Ethics Officer
one month before ethics approval for your research expires.*

Researcher's name Professor Peter HOWE
Dr Jon BUCKLEY
Ms Alicia THORP (to receive correspondence)

Title of project Development and nutritional evaluation of novel foods based on a unique
combination of soy and dairy products

and protocol number P075/04

Number of subjects 45

Location where the project is conducted Nutritional Physiology Research Facility
University of South Australia, City East Campus
Bonython Jubilee Building

Date original approval was granted 3 May 2004

Anticipated completion date December 2005

Reason for extension Due to initial difficulties with the provision of an adequate variety of experimental foods, retention of subjects in the first phase of the study was poor. Out of 55 subjects initially recruited to commence the dietary trial in July 2004, only 35 ended up completing the study in its entirety in December 2004, a shortfall of 10 from our target of 45 completions. Therefore we are seeking an extension on the current ethics approval so we may complete a second smaller cohort of approximately 20 subjects in the second half of this year in order to ensure that we achieve our required total of at least 45 subjects completing the study.

Were there any deviations from the approved ethics protocol? YES/NO

If YES, has HREC been advised of these changes? YES/NO

Were there any adverse effects reported? YES/NO

Please attach a short interim report, indicating how data collection is progressing and detailing any deviations from or amendments to your protocol.

Analysis of both chronic and acute markers of vascular dysfunction in addition to blood lipid profiles and anthropometric measurements of subjects who completed the dietary trial in 2004 is currently underway with the results anticipated to be complete for distribution in late April 2005. Trends indicate the likelihood of demonstrating significant effects of the soy diet with additional subject numbers.

Researcher's signature

Supervisor's signature
(if applicable)



OFFICE OF THE DEPUTY VICE-CHANCELLOR (RESEARCH)

SABINE SCHREIBER
SECRETARY
HUMAN RESEARCH ETHICS COMMITTEE

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CRICOS Provider Number 00123M

25 August 2004

Professor PRC Howe
Physiology

Dear Professor Howe

PROJECT NO: *Development and nutritional evaluation of novel foods based on a unique combination of soy and dairy products*
H-28-2004

I write to advise you that the Human Research Ethics Committee has approved the above project. Please refer to the enclosed endorsement sheet for further details and conditions that may be applicable to this approval.

Approval is current for one year. The expiry date for this project is: 30 June 2005

Where possible, subjects taking part in the study should be given a copy of the Information Sheet and the signed Consent Form to retain.

Please note that any changes to the project which might affect its continued ethical acceptability will invalidate the project's approval. In such cases an amended protocol must be submitted to the Committee for further approval. It is a condition of approval that you immediately report anything which might warrant review of ethical approval including (a) serious or unexpected adverse effects on participants (b) proposed changes in the protocol; and (c) unforeseen events that might affect continued ethical acceptability of the project. It is also a condition of approval that you inform the Committee, giving reasons, if the project is discontinued before the expected date of completion.

A reporting form is available from the Committee's website. This may be used to renew ethical approval or report on project status including completion.

CE MORTENSEN
Convenor
Human Research Ethics Committee



OFFICE OF THE DEPUTY VICE-CHANCELLOR (RESEARCH)

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CRICOS Provider Number 00123M

Applicant: Professor PRC Howe

Department: Physiology

Project Title: *Development and nutritional evaluation of novel foods based on a unique combination of soy and dairy products*

THE UNIVERSITY OF ADELAIDE HUMAN RESEARCH ETHICS COMMITTEE

Project No: H-28-2004

RM No: 0000005953

APPROVED for the period until: 30 June 2005

on the basis of: (i) the Volunteer Information Sheet dated 21.5.04, and (ii) the study being conducted under the Clinical Trial Notification Scheme. It is noted that the study will involve Ms Alicia Thorp, PhD candidate.

Refer also to the accompanying letter setting out requirements applying to approval.

Professor CE Mortensen
Convenor

Date: 30 JUN 2004



OFFICE OF THE DEPUTY VICE-CHANCELLOR (RESEARCH)

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21 March 2005

Professor PRC Howe
Physiology

Dear Professor Howe

PROJECT NO: *Development and nutritional evaluation of novel foods based on a unique combination of soy and dairy products*
H-028-2004

Thank you for your report on the above project. I write to advise you that I have endorsed renewal of ethical approval for the study on behalf of the Human Research Ethics Committee.

The expiry date for this project is: 30 June 2006

Where possible, subjects taking part in the study should be given a copy of the Information Sheet and the signed Consent Form to retain.

Please note that any changes to the project which might affect its continued ethical acceptability will invalidate the project's approval. In such cases an amended protocol must be submitted to the Committee for further approval. It is a condition of approval that you immediately report anything which might warrant review of ethical approval including (a) serious or unexpected adverse effects on participants (b) proposed changes in the protocol; and (c) unforeseen events that might affect continued ethical acceptability of the project. It is also a condition of approval that you inform the Committee, giving reasons, if the project is discontinued before the expected date of completion.

A reporting form is available from the Committee's website. This may be used to renew ethical approval or report on project status including completion.

Yours sincerely

Associate Professor Garrett Cullity
Convenor
Human Research Ethics Committee



THE UNIVERSITY OF
WESTERN AUSTRALIA

Research Ethics
Research Services
M459

35 Stirling Highway, Crawley, WA 6009
Telephone: (08) 9380 3703
Facsimile: (08) 9380 1075
Email: kkirk@admin.uwa.edu.au
WWW: <http://www.research.uwa.edu.au/hethics.html>

Our Ref. RA/4/1/0982

25 May 2004

Dr T A Mori
Medicine - M570
RPH

HUMAN RESEARCH ETHICS COMMITTEE

Project: Development and nutritional evaluation of novel foods based on a unique combination of soy and dairy products

Please be advised that ethical approval of the above project has been granted by the Human Research Ethics Committee.

The Committee is bound by NHMRC Guidelines to monitor the progress of all approved projects until completion to ensure that they continue to conform to approved ethical standards.

The committee requires that all Chief Investigators report **immediately** anything that might affect or impact upon ethical approval of the project, including adverse events affecting subjects.

Approval should be sought in writing **in advance** for any amendments to the original application. You are also required as a condition of this approval to inform the Committee if for any reason the research project is discontinued before the expected date of completion.

An annual report for completion will be sent to you twelve months from this date.

Please note that approval has been granted for a period of four years. Initial approval is for a period of one year, and, thereafter for future periods of one year at a time subject to the receipt of satisfactory annual reports. At the end of the four-year period you will be required to complete a new "Application to Undertake Research Involving Human Subjects" should you wish to continue with your research. However, in special circumstances, the Chair has the authority to extend the approval period in order to complete a project.

Please quote Project No 0982 all correspondence associated with this study.

Yours sincerely

KATE KIRK
Administrative Officer
(Human Research Ethics Committee)

Alicia Thorp

From: Vicki Allen
Sent: Friday, 2 March 2007 11:35 AM
To: Alicia Thorp
Cc: Peter Howe
Subject: Ethics protocol P012/07 "Effect of isoflavone supplementation on vascular and cognitive function in healthy males".

Importance: High

Attachments: Conditions.March 2004.doc

Dear Alicia

Re: Ethics protocol P012/07 "Effect of isoflavone supplementation on vascular and cognitive function in healthy males".

Thank you for providing the amendments and/or additional information requested by the University's Human Research Ethics Committee (Letter dated 23 February 2007).

I am pleased to advise that your protocol has been approved.

Please regard this email as formal notification of approval.

Ethics approval is always made on the basis of a number of conditions detailed in the attachment; it is important that you are familiar with, and abide by, these conditions. It is also essential that you conduct all research according to UniSA guidelines, which can be found at <http://www.unisa.edu.au/res/ethics/default.asp>

Best wishes for your research.

Regards, Vicki



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2004.doc (39 ...)

Vicki Allen
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