

**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**

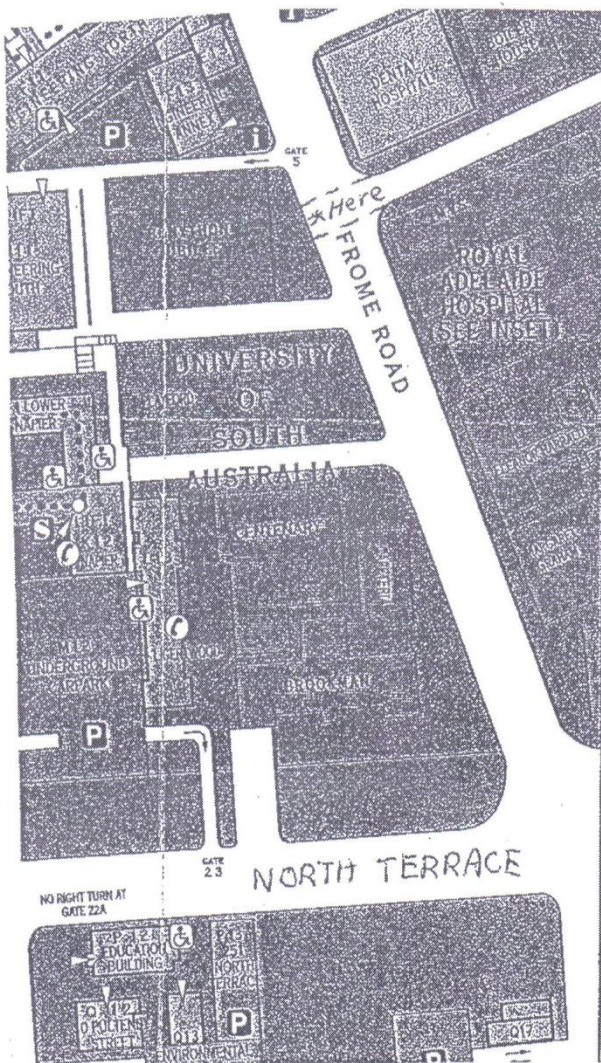
Dear Participant

Thank you for volunteering for the Soy Dairy Health Study. The clinic you will attend for the study is located in the Bonython Jubilee Building at the University of South Australia, City East Campus. The entrance to the building is situated directly opposite the IMVS building and Dental Hospital on Frome Rd. A set of pedestrian lights on Frome Rd leads to the front of the building. Attached to the entrance doors is a sign for 'Breastscreen SA'

Once you have entered the building, walk down a small flight of stairs and at the bottom, turn right. You will see a sign to your right on the wall saying 'Nutritional Physiology Research Facility'. Please enter the first door on your right.

Kind regards,

Alicia Thorp



Ticket parking is available behind the zoo and botanic gardens, along Queen Victoria Drive or Frome Road.

Alternatively, our facility has a private parking bay (nos. 73) located next to the Bonython Jubilee Building. You can access this park by entering the university at Gate 5 when driving north down Frome Rd. (entrance is directly after set of pedestrian lights). If using this parking bay please obtain a permit from one of the staff at our clinic.

There are also 30 minute loading zones in the same area that would be suitable for parking during a screening visit.

# Nutritional Physiology Research Group



University of Adelaide and University of South Australia



## SOY DAIRY STUDY 2004 SCREENING INTERVIEW

SCREENING ID: Sc SD \_\_\_\_\_ APPOINTMENT DATE & TIME \_\_\_\_\_

FIRST NAME \_\_\_\_\_ SURNAME \_\_\_\_\_

Height : \_\_\_\_\_ cm      Weight: \_\_\_\_\_ kg      BMI: \_\_\_\_\_

Waist circumference: \_\_\_\_\_ cm      Hip circumference: \_\_\_\_\_ cm

WHR \_\_\_\_\_

DOB \_\_\_/\_\_\_/\_\_\_      Age: \_\_\_\_\_

### STUDY CRITERIA:

#### Inclusion Criteria:

- Total Cholesterol > 5.5mmol/L

#### Exclusion Criteria

- History of peripheral vascular disease, stroke, cardiovascular or renal disease
- Known presence of Type 1 or 2 diabetes
- Height: <101cm or >255cm (limitation of Cardiovascular Profiler instrument)
- Eat soy products > 2 times/week or plant sterol enriched margarines
- Take anti-hypertensive and / or lipid lowering medication
- Receiving HRT
- Have a blood borne virus
- Unable to consume test foods due to intolerances, taste preferences etc
- Take phosphodiesterase inhibitors eg. Viagra, Levitra

**BLOOD PRESSURE** (3 measurements recorded, 1 min apart, seated, not talking):

Cuff size: M / L

	SYSTOLIC BP	DIASTOLIC BP	PULSE
1			
2			
3			
4			
AVERAGE			

**BLOOD TEST:**

Time: \_\_\_\_\_

Fasting: Y / N

Alcohol in last 24hrs: Y / N    Type/amount \_\_\_\_\_

Vein Code: \_\_\_\_\_

Comments: \_\_\_\_\_

**VISITS:**

**What two consecutive weekdays would suit you best to attend fasting testing sessions**

Monday     Tuesday     Wednesday     Thursday     Friday

**What time would best suit you for a 1.5 hr testing session.**

\*Please note these are fasting visits.

7.30-9.00 am   

9.00-10.30 pm   

10.30-12.00 pm   

Investigator: \_\_\_\_\_

Screening Code:

---

**Investigator use only**

Total Cholesterol \_\_\_\_\_ mmol/L

Eligible for study     Yes     No

Group \_\_\_\_\_

Ineligibility reason \_\_\_\_\_

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**Ms Alicia Thorp**  
Nutritional Physiology Research Facility  
Room BJ1-61, Bonython-Jubilee Building  
School of Health Sciences  
University of South Australia  
Adelaide, SA 5000  
Ph: 8302 2097

Dear

Thank you for expressing an interest in participating in the **2004 Soy Dairy Health Study** aimed at examining the effects of dairy and soy foods on cholesterol reduction and blood vessel function. The results from your screening visit at our research facility indicate that you are eligible to participate in the trial scheduled to commence on July 19<sup>th</sup>. I have attached a copy of your personal results.

If you are still interested in being a participant in the trial I would ask that you attend an information session during which I will explain in detail exactly what we will be asking you to do over the 18 weeks of the trial. You will also have the opportunity to raise any questions you may have as well as be introduced to other members of the research team, and to sample some of the foods that will be provided for the study

The information sessions are scheduled for the evenings of:

**Thursday 1<sup>st</sup> July, 6.15-7pm**  
**Wednesday 7<sup>th</sup> July, 6.15-7pm**

I would appreciate it if you could please let me know which of these two sessions you would be able to attend.

Both sessions will be held in the room next to the clinic where you came for your screening visit

If you have any questions or would like to discuss your screening results please feel free to contact me on 8302 2097 or email me at [alicia.thorp@unisa.edu.au](mailto:alicia.thorp@unisa.edu.au).

Thank you again for your interest in being a participant in our study, and I look forward to hearing from you soon.

Yours sincerely

Ms Alicia Thorp  
*for* Prof Peter Howe  
Head, Nutritional Physiology Research Group

**Below are your results from the screening visit:**

<b>Measurement</b>	<b>Result</b>	<b>Recommended Range</b>
Fasting total cholesterol	6.16	<b>Less than 5.5 mmol/L</b>
Systolic blood pressure	111	<b>Less than 140 mmHg</b>
Diastolic blood pressure	70	<b>Less than 90 mmHg</b>
Weight	90.6 kg	-
Height	172.2 cm	-
Body Mass Index	30.6	<b>20-25</b>
Waist circumference	90.5 cm	<b>Men &lt; 102 cm</b> <b>Women &lt; 88 cm</b>
Hip circumference	120 cm	-
Waist to Hip ratio	0.75	<b>Men ≤ 0.95</b> <b>Women ≤ 0.80</b>

# SOY DAIRY HEALTH STUDY 2004

## 45 MINUTE VISIT

### **INFORMATION ON BODY MEASUREMENTS, BLOOD TAKING AND DIETARY ANALYSIS**

The visit will begin with you arriving at the clinic in a fasted state (and if necessary, you handing in your overnight urine collection bottle). Body measurements including height, weight, waist and hip measurements will then be recorded (same as what was done at your initial screening visit). A total body fat % reading will also be taken at the same time your weight is being assessed using the clinic scales.

You will then be asked to sit down and a fasting blood sample will be collected. After this, you will have the opportunity to hand in your completed weekly food record sheets and 3 day weighed food diaries (which you will have filled out during the week beforehand) as well as picking up your next 2- week food preference form and food parcel (which will have been prepared from your previously submitted 2-week food preference form).

You will then be asked to complete a brief Food Acceptability Questionnaire (only at weeks 6, 12 and 18 in the study) that asks questions related to the taste, your preference of the trial foods etc. you've just finished consuming for each six week dietary phase. Wanda, our dietician, will also be available during this time to discuss any issues you may be having regarding weight management or how you can best incorporate the trial foods into your diet. She will also be providing feedback on your 3-day weighed food records during this time.

# SOY DAIRY HEALTH STUDY 2004

## 1.5 HOUR VISIT

### INFORMATION ON ULTRASOUND & ARTERIAL COMPLIANCE MEASUREMENTS

Today you will have your blood vessel function measured by (1) ultrasound and (2) arterial compliance assessments.

The visit will begin with you arriving at the clinic in a fasted state (and if necessary, you will hand in your filled overnight urine collection bottle). You will then have your weight recorded and be asked to lie down for 5-10 minutes to allow your blood pressure to stabilise, during which time a fasting blood sample will be collected. Still in a lying down position, your right wrist will be placed in a comfortable support and a sensor attached to the arterial compliance machine will be positioned on the skin of your wrist where there is a visible pulse. A blood pressure cuff will also be placed on the left upper arm to allow us to take blood pressure measurements. The arterial compliance test will then be performed in triplicate, during which time we will ask you to lie still and not talk. (each test lasts approximately 5 minutes). Once complete, the sensor from the wrist and the blood pressure cuff will be removed.

Still lying down, a blood pressure cuff will be placed around the lower right arm and a hand held scanner attached to the ultrasound machine will be placed over the large artery in the arm (brachial artery) to capture its image at rest. The blood pressure cuff will then be inflated (to 200mmHg) and maintained at this pressure for 5 minutes. After 5 minutes, the cuff will be released and the change in the diameter of your artery in response to the release of the cuff will be measured by the ultrasound machine.

After a 5-10 minute recovery period, half a nitroglycerin\* tablet (300 µg) will be placed under your tongue for 3 minutes which will dilate blood vessels and increase blood flow through the vessels. Once 3 minutes is over you will remove the tablet from your mouth (if not already dissolved) and ultrasound images of the brachial artery will be recorded every minute for a total of ten minutes.

\*NTG, or nitroglycerin, is a non-prescription drug, which can be purchased over the counter at any pharmacy. It is used to prevent or relieve chest pain and works by relaxing blood vessels to the heart, so the blood flow and oxygen supply to the heart is increased. Like any drug, there may be some potential side effects that may occur from taking nitroglycerin, they include: headache, rash, dizziness, upset stomach, flushing (feeling of warmth), blurred vision, dry mouth, chest pain and fainting.

**If you are feeling uncomfortable at any time, please let one of us know.**



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## VOLUNTEER CONSENT FORM

### Development and nutritional evaluation of novel soy based foods

**STUDY INVESTIGATORS:** Ms. Alicia Thorp  
Prof. Peter Howe  
Dr. Karen Murphy  
Dr. Jon Buckley

1. I have read the Information Sheet, and the nature and the purpose of the research project and the risks inherent in my participation have been explained to me. I understand and agree to take part.
2. I understand that I may not directly benefit from taking part in the study.
3. I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. I understand that I can withdraw from the study at any stage and that this will not affect my rights or the responsibilities of the researchers in any respect.
5. I have had the opportunity to discuss taking part in this study with a family member or friend.
6. I understand that I am a volunteer in this project and will receive no payment for my participation.
7. I confirm that I am over 18 years of age.

Name of Participant .....

Signed .....

Dated .....

I have explained the study to the participant and consider that he/she understands what is involved.

Signed .....

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Dear

Thank you for expressing an interest in participating in the **2004 Soy Dairy Health Study**. Unfortunately based on information you provided in your Diet and Lifestyle Questionnaire, it appears that you do not meet our strict inclusion criteria for this particular study. Although you are not eligible to participate in this study, we have similar studies running from time to time and we will notify you of any future studies that may be of interest to you.

If you have any questions about why you were not eligible to participate in this study please feel free to contact me on 8302 2097 or email me at [alicia.thorp@unisa.edu.au](mailto:alicia.thorp@unisa.edu.au).

We at the Nutritional Physiology Group appreciate that the ongoing success of our studies relies heavily on people like yourself, who are willing to volunteer their time and efforts for scientific research, and we would like to thank you very much for your interest in our study.

Yours sincerely

Ms Alicia Thorp  
*for* Prof Peter Howe  
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Dear

Thank you for expressing an interest in participating in the **2004 Soy Dairy Health Study**. Unfortunately for us, your total cholesterol reading was below 5.5 mmol/L. This means that we are unable to include you in this study, but does indicate that you have a nice healthy cholesterol level. Although you are not eligible to participate in this study, we have similar studies running from time to time and we will notify you of any future studies that may be of interest to you.

I have attached your personal results from your screening visit on the following page. If you have any questions about these results, or why you were not eligible for this study, please feel free to contact me on 8302 2097 or email me at [alicia.thorp@unisa.edu.au](mailto:alicia.thorp@unisa.edu.au).

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Dear

Thank you for expressing an interest in participating in the **2004 Soy Dairy Health Study**. Unfortunately because you are currently taking blood pressure medication and we are assessing the effects of soy on blood pressure we are unable to include you in this study. Although you are not eligible to participate in this study, we have similar studies running from time to time and we will notify you of any future studies that may be of interest to you.

I have attached your personal results from your screening visit on the following page. If you have any questions about these results, or why you were not eligible for this study, please feel free to contact me on 8302 2097 or email me at [alicia.thorp@unisa.edu.au](mailto:alicia.thorp@unisa.edu.au).

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