University of South Australia

Human Ethics Application

Application ID :	0000032778
Application Title :	Dietary influences on insulin sensitivity: Randomized crossover study
Date of Submission :	08/04/2014
Primary Investigator :	Mrs Yoona Kim
Other Investigators :	AsPr Jennifer Keogh
	Prof Peter Clifton

Create New Ethics Application

Create New Ethics Application

The following provides brief information on how to complete an online ethics application. For more detailed information, please refer to the User Guides available at the UniSA website. Please note that there is also a User Guide for the Principal Supervisor to assist supervisors with the review of student applications. The User Guides also detail the process to follow should you be required to respond to reviewer's comments.

The System allows researchers to complete and submit human ethics applications electronically. Applicants navigate their way through the application by answering a number of questions. Sections, pages and / or questions appear based on the answers to previous questions therefore it is advisable that you complete questions sequentially in order to avoid skipping questions unintentionally. At times, word limits may prevent you from providing all the information you need to include. If this is the case, please include the necessary information as either a separate document and add it as an attachment (function available on the left hand menu available from the Attachments Section), or as a page comment. Please refer to the User Guides if you are unsure how to use these functions.

Please ensure you enter requested information in the sections available on the screen's left hand menu (Investigators, Attachments etc). Submitted applications that do not contain the required information will be returned to you and therefore the review process will be delayed. Refer to the User Guides if you are unsure how to use these functions.

ANSWERING QUESTIONS
It is important to take time to answer each question carefully and fully before progressing to the next question. By doing so, you will minimise the request for more details from the reviewers and/or prevent potential system errors.

Please note that the system will time out after 40 minutes of inactivity and any unsaved answers will be lost.
Each section of the online form can be saved by clicking the 'save' icon on the toolbar at the top right corner of the page. Each page is saved automatically when you click the green arrow to move on to the next section.

The research activity must not commence until ethics approval is finalised.*

☑ I agree

Investigator

Investigator

1 Is primary applicant a student? Please select 'Yes' if you are a student; if you are a staff member answer 'No'*

- (•) Yes
- ( ) No

2 **Please ensure that you mark the Primary Contact (usually the Chief Investigator) for this protocol as "Primary".**
(Please click on the name and select 'Yes' to 'Primary?' field).

Use the Search Name/ID to search for and add other investigators. Select their position/role from the dropdown box.

To save your changes, click the green tick at the right bottom corner of the form. *

1	Given Name	Yoona
	Surname	Kim
	Full Name	Mrs Yoona Kim
	System code of Position held	Chief Investigator
	User Person Code	110139456
	Primary?	Yes
	AOU system code	PMB
	Organisation	
	Organisation Name	

2.1 Please provide your contact phone number if you agree to it being used by Ethics Administrators to follow up any points requiring clarification.

0469599045

Principal Supervisor

Supervisor

Only the details of your principal supervisor (i.e. the person responsible for reviewing your application) can be included here.

If you are having trouble finding your supervisor's details, please try searching by surname only. *

1	Given Name	Jennifer Beatrice
	Surname	Keogh
	Full Name	AsPr Jennifer Keogh
	System code of Position held	Supervisor
	User Person Code	125601

	Primary?	No
	AOU system code	PMB
	Organisation	
	Organisation Name	
	Supervisor person code	
2	Given Name	Peter Marshall
	Surname	Clifton
	Full Name	Prof Peter Clifton
	System code of Position held	Supervisor
	User Person Code	127633
	Primary?	No
	AOU system code	PMB
	Organisation	
	Organisation Name	
	Supervisor person code	

Prior Assessment

Project Core Details

Primary AOU*

Sch Pharmacy & Medical Sciences

Ethics category code*

Human Ethics

Application Title*

Dietary influences on insulin sensitivity: Randomized crossover study

Non-UniSA HREC

UniSA HREC seeks to avoid the unnecessary duplication of ethical review. If your ethics application has already been approved by another Australian Human Research Ethics Committee, you should attach a copy of the full application submitted to the other HREC and the approval letter. The remainder of this application form will then be automatically shortened. UniSA HREC will review these documents, and if satisfied, will ratify the decision of the other committee.

1.1 Has another Human Research Ethics Committee (other than UniSA) reviewed this research project before and does this clearance/approval accurately describe the project as it is to be conducted? *

- ○ Yes
- ◉ No

UniSA HREC

2.1 Is this application a resubmission of an application that was considered by UniSA HREC and the decision was 'Not Approved: Resubmit', 'Not Approved' or "Approved subject to" and the status has expired (ie amendments were not made within the 6 month timeframe). Please note if your application is "Approved subject to" and 6 months **has not** lapsed then you should use the original application submitted to make the required changes. *

- ○ Yes: Not approved: resubmit
- ○ Yes: Not Approved
- ○ Yes: Approved subject to and the status has expired
- ◉ No

Project Scope

Project Scope

11.1 Is the activity archival research? A large proportion of activity involving the analysis of documents, publicly available information, or previously collected data may be outside the scope of the University's human research ethics arrangements. *

- ○ Yes
- ◉ No

11.2 Is the work being conducted only for UniSA administrative / service delivery purposes? *

- ○ Yes
- ◉ No

12.1 Should the work be characterised as quality assurance or an audit, rather than human research within the scope of the University's human research ethics arrangements? *

- ○ Yes
- ◉ No

12.2 Is the work a practical exercise or test conducted for teaching purposes in a University administered facility? (Please refer to Appendix 2 of Guidelines for Evaluation Activities Involving UniSA Students and Staff) *

- ○ Yes
- ◉ No

13.1 Is the work a routine experiment or procedure conducted for teaching purposes in a University administered facility? *

- ○ Yes
- ◉ No

13.2 Is the work / data collection conducted by a student only for teaching / learning purposes? *

- ○ Yes
- ◉ No

Initial Check

The purpose of this 'Initial Check' is to direct your ethics protocol to the appropriate level of review.

If you were **not** notified that your protocol was assessed as Exempt or Negligible risk, please click **Continue.**

However, if the previous screen stated that your protocol was assessed as being either Exempt or Negligible risk, please click **Finish**.

*

- ◉ Continue
- ○ Finish

Project Details

Ethics Training

3.1 Have you had human ethics training in the last 24 months? (Please do not include training you have attended regarding how to use the online ethics system)*

- ○ Yes
- ◉ No

Project Type

4.1 Main type of research (e.g. staff, PhD). *

PhD

4.1.2 **Please note that, if you are a student applicant, your application will be forwarded to your principal supervisor once submitted for their approval. If they are satisfied with your application it will be forwarded to the relevant review group. If your supervisor requires changes to be made then your application will be returned to you to make the required changes.**

4.2 Are there any other types of research involved (not identified in 4.1) . Please select all that apply*

- ☐ None
- ☐ Honours
- ☐ Course Approval
- ☐ PhD
- ☐ Masters by Coursework
- ☐ Masters by Research
- ☐ Professional Doctorate
- ☐ Undergraduate
- ☐ Graduate Diploma/Graduate Certificate
- ☑ Staff
- ☐ Other

4.3 Please list which school(s) the UniSA researcher(s) is/are from?*

Sch Pharmacy & Medical Sciences

Project Details

5.1 Plain English title*

Dietary influences on insulin sensitivity: Randomized crossover study

5.2 What are the aims of your research?*

Dietary patterns such as high red meat (refined and processed) and refined grains are believed to be harmful and others including low fat dairy, nuts, legumes and whole grains beneficial in the prevention of type 2 diabetes. This research aims to investigate the effect of these dietary patterns on insulin resistance in the absence of weight loss and exercise, and to clarify the potential biological mechanism of the effects of glucose metabolism behind these dietary patterns.

5.3 List your research questions or hypotheses. Your protocol should clearly identify the questions which you want your research to answer. *

We hypothesise that red and processed meat and refined grains negatively affect insulin sensitivity or insulin secretion, compared with low fat dairy, legumes, nuts and whole grains.

5.4 Explain the need for, and value of, your research. Place the aims in the context of existing research or practice AND what your study does to add to existing literature. (You must include a list of not more than 10 key references as an attachment to support your answer to this question. These are to be attached to the Attachments section of this application).*

The prevalence of diabetes in Australia has grown rapidly from 1.5% between 1989¿90 to 4.2% between 2011¿12 (Australian Institute of Health and Welfare 2013). When combined with pre-diabetes-impaired glucose tolerance (IGT) and impaired fasting glucose (IFG), the figures would double[1]. The Australian Diabetes Council reports that `approximately 3.61 million Australians have diabetes or pre-diabetes¿[2] or 16% of the population[2]. People with type 2 diabetes are 3¿4 times more likely to die from cardiovascular disease than the general population. This situation puts an enormous economic burden on Australian society. Dietary choice directly or indirectly contributes to the risk of developing type 2 diabetes with the associated complication of cardiovascular diseases. Some certain dietary patterns such as high red meat (refined and processed) and refined grains are believed to be harmful and others including low fat dairy, nuts, legumes and whole grains beneficial in the prevention of type 2 diabetes. It is unclear if healthy eating alters insulin resistance in the absence of weight loss and exercise. Clarification of the potential biological mechanism of the effects of diet glucose metabolism is an important area.

In a combined analysis of the 37,083 men in the Health Professionals Follow-Up Study (1986-2006), 79,570 women in the Nurses' Health Study I (1980-2008), and 87,504 women in the Nurses' Health Study II (1991-2005), both unprocessed and processed red meat intakes are correlated with T2D risk in each cohort. In the most recent meta-analysis (442,101 participants and 28,228 diabetes cases): the risk ratios (RR) (95% CIs) were 1.19 (1.04, 1.37) and 1.51 (1.25, 1.83) for 100 g unprocessed red meat/d and for 50 g processed red meat/d, respectively [3]. Therefore, this suggests that red meat consumption,especially, processed red meat, is associated with the development of Type 2 Diabetes [3]. However there are no clinical intervention studies investigating the effect of a high red and processed meat diet on insulin sensitivity.
A meta-analysis of population-based cohort studies with total dairy products, low-fat dairy products, cheese and yogurt, indicates an inverse association between intake of low-fat dairy, low-fat milk, cheese and yogurt and NIDDM with no association the between the intake of full-fat dairy and total and full-fat milk and NIDDM[4]. A recent intervention study in 23 overweight and obese subjects shows that intake of 4 servings/d of low-fat dairy milk and yogurt products for 6 months compared with 2 servings per day over 6months may reduce insulin resistance without weight gain and negative changes of lipid profiles[5]. Few interventional studies have been undertaken [6] and none have used dynamic measures of glucose metabolism.
Meta-analysis of 7prospective cohort studies indicate that increased intake of magnesium rich foods such as nuts, beans, whole grains is associated with the improvement of insulin sensitivity [7]. Two large prospective U.S cohorts among 76,464 women in the Nurses¿ Health Study (1980¿2010) and 42,498 men in the Health Professionals Follow-up Study (1986¿2010) represent the frequent consumption of nuts significantly reduces total and case-specific mortality[8]. A systemic review and meta-analysis of prospective studies revealed inverse associations between the intake of whole grains including whole grain bread, whole grain cereals, wheat bran and brown rice and risk of type 2diabetes, as well as the correlation between white rice and increased risk[9]. Meta-analysis from 15 cohort studies empathizes the importance of a healthy diet in lowering fasting glucose and fasting insulin levels regardless of genotype[10].

5.5 Please describe your research design and methodology (e.g. where will the data collection occur, what will participants be asked to do during the course of data collection, how long will the interview/focus groups/filling out the questionnaire take, etc).*

This study is a randomized cross-over trial with two different diets: one is a dietary pattern high in red and processed meat and refined grains, and the other high in legumes, nuts, whole grains and low fat dairy. 30 participants with IFG/IGT and 30 people with normal glucose levels group will be recruited by public advertisement. Subjects will be overweight or obese (BMI 25-45) over age of 18. Glucose tolerance will be assessed by a 75g OGTT at the initial visit.This study will run 10 weeks and 2 days with 8 visits. The intervention will consist of two 4 week weight stable diet periods with a 2 week washout period on usual diet. All participants will be provided with full dietary instructions. Energy intake will be restricted approximately 10MJ/day for men and 8.5MJ/day for women. The two diets will be designed for individuals depending on their weight and activity levels. The dietary design of this project has been virtually run by foodworks 7 based on the overweight and obese Australian dietary habits. At baseline height and weight will be measured and a DEXA scan will be performed for assessment of total lean body mass. Specific instructions on dietary changes will be given d in conjunction with individual¿s 24hour food record. Participants will be provided with a scale to measure the quantity of food. Written Informed consent will be obtained from all participants. Participants will fortnightly visit the School of Pharmacy and Medical Sciences and submit a 3-day weighed food record and daily checklists which will be analysed by Foodworks 7.
Insulin sensitivity will be assessed by continuous low dose insulin (25mU/kgh) and glucose (4 mg/kg.min) infusion test (LDIGIT) lasting150 min after a 10h overnight fast. Meal tolerance test (MTT) will be performed. Insulin sensitivity under fasting conditions will be calculated with Homeostasis Model Assessment (HOMA) using fasting insulin and glucose values.
GLP1 and GIP (Circulating levels of human GLP-1 and GIP will be determined by enzyme-linked immunosorbent assay (ELISA) using the GLP-1 amide/prepro-glucagon amide enzyme immuno assay EIA kit and the human GIP assay kit, respectively. Magnesium, creatinine and potassium will be measured in a spot urine sample. Measurement of AGEs will be performed with HPLC. Inflammatory markers (CRP, IL-6, TNF-¿)[19] and lipid profiles will be analysed in fasting blood samples.

Resources

Project Funding

6.1 Have you applied for funding for this project from any external source?*

- ○ Yes and application for the funds has been successful
- ○ Yes but the outcome of the application is not yet known
- ◉ No

6.5 Will the project be supported in ways other than direct funding (eg in-kind support/equipment by an external party)? *

- ○ Yes
- ◉ No

Ownership of Data

8.1 Detail who will own the data and the results of your research (student researchers normally own their own research and data unless there is a written agreement between the student and the University / third party; staff research and data is normally owned by UniSA). Please select all that apply.*

- [x] UniSA
- [x] Student researcher
- [ ] Other

8.2 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?*

- ○ Yes
- ◉ No

8.3 Please note that it is the researcher's responsibility to ensure that, where required, an appropriate agreement is in place. If you are unsure whether this is needed, please consult the Intellectual Property website . Do you require an agreement regarding ownership or do you currently have an agreement in place?

Please note that a signed agreement will usually be required where:
- A research team includes both students and staff; or
- Where researchers from different institutions are collaborating on a project.*

- ◉ An agreement is required
- ○ A signed agreement is in place
- ○ An agreement is not required

Please note that you must inform UniSA HREC once the agreement has been signed. Final ethics approval cannot be given until confirmation is received.

Data: storage, access, disposal

9.1 The information which will be stored at the completion of this project is of the following type(s). Please select all that apply.*

- [x] Individually identifiable
- [ ] Re-identifiable
- [ ] Non-identifiable

9.1.1 Give reasons why it is necessary to store information in identifiable or potentially identifiable form (coded).*

In case any individual particpant data needs to be identified for any reason after the completion of the project.

9.2 Where will the data be stored? University policy requires researchers to store a copy of the data onsite at UniSA, usually in the relevant School Office (please specify the campus and office/room location e.g. Mawson Lakes Campus, RM GP2-19). Please refer to the University's Ownership and Retention of Data Policy.*

Password protected computer in a locked office at City East Campus, Playford Building Level 1, Office P1-18.

9.3 For how long will the information be stored after the completion of the project? Why has this period been chosen? *

15 years.Per the UniSA'Ownership and Retention of Data' Guidelines, Policy:Res-17.0 for Clinical Trials (research involving humans).

9.4 In what formats will the information be stored during the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, USB memory stick, videotape, film) *

Paper data collection forms and computer files on hard disk.

9.5 How will information, in all forms, be disposed of after the retention time has lapsed? (Please refer to the Ownership and Retention of Data Policy. The Head of School (or equivalent) must be aware of this process).*

Data collection form will be shredded and electronic files deleted. Written approval from head of school or relevant management will be obtained before any disposal or destruction of research data, primary materials or associated research records.

9.6 Will any other individual(s), organisation(s) or researcher(s) (other than those listed on the Investigators & Supervisors section) have authority to use or have access to the information?*

- ○ Yes
- ◉ No

9.7 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during the research project. (eg. Will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)*

Electronic data will be kept on a password protected file: paper forms will be kept in a locked filling cabbinet in a locked office. Identification will be removed at project completion.

9.8 If the principal researcher leaves UniSA prior to the finalisation of data collection and/or before the storage retention time has lapsed, the researcher(s) will comply with the Universities Ownership and Retention of Data Policy in relation to the storage of data / information collected for, used in, or generated by this project.*

- ◉ I agree
- ○ I do not agree

Insurance

10.1 Please refer to the Insurance Cover website: Do you require insurance cover for this project?*

- (●) Yes
- ( ) No

10.1.1 Do you have insurance cover for this project?*

- (●) Yes
- ( ) No

10.1.2 **Please note that you must provide UniSA HREC with a copy of the insurance cover confirmation letter/email. You cannot commence your research until insurance cover is confirmed. Once received, please upload a copy of the confirmation e-mail under the 'Attachments' section of this application or forward the email to ethics@unisa.edu.au.**

Research type and participants

Research type

14.1 This project involves: Research using...(Please select all that apply.)*

- [ ] Qualitative methods
- [x] Quantitative methods, population level data or databanks, e.g. survey, epidemiological research
- [ ] None of the above

14.2 What research methodologies will you use? (Please select all that apply.) *

- [ ] Anonymous questionnaires
- [ ] Internet questionnaires
- [ ] Questionnaires requesting intimate personal, identifying, or sensitive information
- [ ] Other questionnaires
- [x] Face to face interviews which do not request personal or sensitive information
- [ ] Face to face interviews which request personal or sensitive information
- [ ] Telephone survey which does not request personal or sensitive information
- [ ] Telephone survey which requests personal or sensitive information
- [ ] Focus groups
- [ ] Action Research
- [ ] Evaluation research
- [ ] Observation of participant's usual activities
- [ ] Observation of an activity set up for the purposes of the study
- [ ] Access to medical records
- [ ] Access to records containing intimate, individually identifiable information, not publicly available
- [ ] Experiment or testing of a procedure, drug or equipment
- [ ] Use of biological hazards, GMOs or pathogenic organisms
- [ ] Use of carcinogenic and/or toxic chemicals, including heavy metals
- [x] Use of Radiation (Ionising and/or Non-ionising, but not Ultrasound)
- [ ] Other

14.2.2 Is it intended that the interview/focus group transcript will be shown or made available to participants?*

- ( ) Yes
- (●) No

14.2.2.2 Why are participants not provided with the transcript of the interview/focus group?*

> Interviews will be individually conducted to gather non-sensitive screening/eligibility data at baseline and further inteviews held to assess compliance to each diet. No group sessions will be held.

14.3 Will you be audio-taping, video-taping, or taking photographs of participants during the course of the study? Please select all that apply.*

- [ ] Audio-taping
- [ ] Videotaping
- [ ] Photographs
- [x] No

Participant information

15.1 How many participant groups are involved in this research project? *

2.00

15.2 Please provide the details as an **attachment** for each participant group. **(To upload your attachment, please click on the Attachments section of the application on the left hand side of the screen)**

15.3 What is the expected total number of participants in this project at all sites?*

60.00

15.3.1 Please provide details of how many participant groups will be involved, the number of participants in each group, the age range of the participant groups, the relevant characteristics of each group and what each participant group will be required to do? e.g. pilot study group, main study group, interview group, focus study group, experimental group, control group etc. If required, please add a document to the Attachments page in response to this question.*

See Attachment

15.3.2 Please justify the chosen sample size.*

25 participants in each group would give 80% power (P<0.05) to assess insulin sensitivity for overweight participants with either NGT or IGT using LDIGIT (Mean= 11.8 and 8.9; SD=5.19) [12]. 30 participants in each group will be recruited in each group allowing a 20% dropout rate.

Selection of participants

16.1 What process(es) will be used to identify potential participants?*

Flyers will be posted around the University and on the public boards.

16.2 Will potential participants be 'screened' or given a test/questionnaire to assess their suitability as a participant for the study?*

- (•) Yes
- ( ) No

16.2.1 How will this be done?*

Anyone that contacts the researchers about the study will be given an information sheet outlining the project and if they are interested in participating, they will be screened to see if they meet the inclusion/exclusion criteria.

16.3 Describe how initial contact will be made with potential participants.*

Contact information will be provided on the flyers, so participants will call or email the researchers if they are interested in learning more.

16.4 Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?*

- (•) Yes
- ( ) No

16.4.1 Please detail how this will be used and/or whether any approval is needed to use this contact method. **Please attach any relevant documents to the Attachments section of this application.***

Flyers will be posted around the University and on the public boards. Flyer attached. We may need to use newspaper advertising.If we advertise, it would be in the Advertiser or Messenger or would go through UniSA marketing for approved formating.

16.5 List the selection and, if appropriate to your study, the exclusion criteria for participants.*

Overweight and obese people with either normal glucose tolerance or prediabetes will be chosen for the general public. Exclusion criteria include anyone aged under 18; anyone with major metabolic illness such as kidney or liver diseases; anyone on medication which can influence glucose metabolism(eg.Metformin).

16.6 If it became known that a person or participant group was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?*

- ( ) Yes
- (•) No
- ( ) Not Applicable

Project start, end, location details

17.1 Will the research be undertaken in Australia?*

- (•) Yes
- ( ) No

17.1.1 In which town(s)/city(ies)/State(s) of Australia will the research be undertaken in? *

Adelaide, South Australia

17.1.2 In how many Australian organisations will the research be conducted? (Please list all organisations where participants will be specifically recruited from e.g. if recruiting UniSA staff or students, you have at least 1 organisation)*

1.00

Please note: you must obtain written approval from the organisations where the research will be undertaken and either attach the letter to the application or forward this to the Ethics and Compliance Officer before final approval can be granted for the project. Please refer to UniSA/organisation approval for additional information on the type of approval needed.

17.1.2.1 Please enter the details for the Australian site(s) where participants will be recruited from, the location of the organisation, the anticipated start date for the site and the anticipated end date for the site.*

University of South Australia
City East Campus, Playford Building
Anticipated start date-May 2014
Anticipated end date-Feb 2017

17.2 Will the research be undertaken overseas?*

- ○ Yes
- ◉ No

17.3 Are there any time-critical aspects of the research project of which review committee should be aware?*

- ○ Yes
- ◉ No

Irregular consent process

Limited disclosure/waive consent

18.1 Does the research involve limited disclosure to participants? Refer to Chapter 2.3 of the National Statement. *

- ○ Yes
- ◉ No

18.2 Are you asking the HREC / review body to waive the requirement of consent? Refer to Chapter 2.3 of the National Statement.*

- ○ Yes
- ◉ No

Covert Observations

19.1 Does the research involve covert observation? Refer to Chapter 2.3 of the National Statement.*

- ○ Yes
- ◉ No

Deception

20.1 Does the research involve deception? Refer to Chapter 2.3 of the National Statement.*

- ○ Yes
- ◉ No

Project Type

Project Type

21.1 Does the research involve any of the following? Please select all that apply.*

- ☐ Drugs; narcotics; poisons; ingestion/injection of placebo, or an invasive procedure administered
- ☑ Clinical trials
- ☐ Cellular therapy
- ☑ Collection and/or use of human samples (eg tissue; blood or other body fluid collection/extraction)
- ☐ Genetic testing and/or genetic research
- ☐ Human gametes or use or creation of human embryos
- ☐ A practice or intervention which is an alternative to a standard practice or intervention
- ☐ Investigating workplace practices which could possibly impact on workplace relationships
- ☐ Conducting the research overseas and recruiting participants
- ☐ None of the above

Clinical trial/ Cellular therapy

You have indicated that this research involves clinical trials and/ or a cellular therapy. Please refer Chapter 3.3 of the National Statement when answering the following questions.

23.1 **The project will be conducted as follows:**

23.1.1 Under the Clinical Trial Notification Scheme (CTN)*

- ○ Yes
- ◉ No

23.1.2 Under the Clinical Trial Exemption Scheme (CTX)*

- ○ Yes
- ◉ No

23.2 Please detail your Data and Safety Monitoring Board (DSMB) and its nominee for this trial.*

not applicable

23.3 **Type of research/trial**

23.3.1 Will a drug / medicine (including a complementary / alternative medicine) be administered?*

- ○ Yes
- ◉ No

23.3.2 Will a medical device be used?*

- ○ Yes
- ◉ No

23.3.3 Will a human somatic cell gene therapy be administered?*

- ○ Yes
- ◉ No

23.3.4 Will a xenotransplant be used?*

- ◉ No
- ○ Yes

23.3.5 Will stem cells (adult or embryonic) be used as therapy?*

- ○ Yes
- ◉ No

23.3.6 Is another type of therapy (not identified in previous questions) to be used?*

- ○ Yes
- ◉ No

Trial Details

24.1 **Provide the following details for the clinical trial protocol:**

24.1.1 Protocol name*

Dietary influences on insulin sensitivity: Randomised crossover study

24.1.2 Protocol version number*

n/a

24.1.3 Protocol version date*

12/03/2014

24.2 If you intend to/have registered this trial in a publicly accessible register, please provide the details.*

Once ethics approval is granted,this trial will be registered with the Australian New Zealand Clinical Trials Registry.

24.3 **Provide the following details for the investigator's brochure/product information (as relevant):**

24.3.1 Title of Investigator's Brochure or Product Information

This question is not answered.

24.3.2 Investigator's brochure version number

This question is not answered.

24.3.3 Investigator's brochure version date

This question is not answered.

Clinical Trial

28.1 **Provide a statement describing the following:**

28.1.1 Method of randomisation*

Participants will be randomised into two groups by using computer generated random numbers.

28.1.2 Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment.*

The dietary intervention is not being compared to a 'standard treatment' but to explore mechanisms responsible for changes in insulin sensitivity.

28.1.3 The justification for the use of placebo or non-treatment control group, including alternative effective treatments and any risk of harm in the absence of treatment.*

n/a

28.1.4 How variations in response will be treated*

n/a

28.1.5 Endpoints*

Primary endpoint will be the assessment of insulin sensitivity and insulin release.

28.1.6 Details of contingencies and management of these*

n/a

28.2 Explain the arrangements in place to ensure there is adequate compensation for participants.*

After participants have completed all study visits, they will receive a gift voucher of $60 per diet in appreciation of their time.

28.3 How many drugs will be used in this research project? (not including the placebo)*

.00

Human Samples

You have indicated that this research involves the collection and / or use of human samples (this includes tissue, blood or other body fluid collection / extraction). Please refer to Chapter 3.4 of the National Statement when answering the following questions.

29.1 Are the risks associated with the research easily minimised or managed?*

- (•) Yes
- ( ) No

29.2 Please provide details. *

Blood samples will be taken by trained staff according to standard procedures and protocols.
Participants will either complete their urine samples at home and bring them in, or when they come in to their appointments.

29.3 What is the nature of the sample(s) you plan to use?*

Fasting blood samples
Spot urine samples

29.4 What is the source of the sample(s) you wish to use? (Please select all that apply.)*

- [x] Collected from participants recruited who are not concurrently undergoing diagnosis or treatment
- [ ] Collected from participants recruited who are concurrently undergoing diagnosis or treatment
- [ ] Obtained from tissue archives/tissue bank
- [ ] Obtained from, or accessed during, autopsy
- [ ] Samples sourced / obtained from overseas

29.4.1 By whom will the sample(s) be collected? *

- (•) A member of the research team
- ( ) A third party

Samples Collected

30.5 In what form will the tissue sample(s) be used by the investigators in the conduct of this project?*

- ( ) Identified
- (•) Potentially identified (i.e. coded)

- ○ De-identified (i.e. Not identifiable, anonymous)

30.6 Will the tissue sample(s) used for this project be destroyed once the project is completed?*

- ○ Yes
- ◉ No

30.6.1 Explain why the tissue sample(s) will not be destroyed; who will have access to them in the future; and whether the tissue samples will be used to establish a tissue bank or genetic register.*

Blood samples may be used for further analysis, for which ethics approval would be sought. Only the researchers involved in this project would have access to those samples. No tissue bank or genetic register would be estabilised .

30.7 Does this research involve the development of a cell line?*

- ○ Yes
- ◉ No

30.8 Provide details of the collection and management of the human sample(s).*

12 blood samples will be collected over 150 miniutes using LDIGIT. The blood sample will be centrifuged and the serum collected and frozen at -80 degrees until needed for analysis.

30.9 Describe how you will ensure that all sample(s) used in this project will be stored securely and describe how you will monitor this as well as the use of the sample(s).*

The samples will be stored in a -80 degree freezer which is alarmed in case of freezer malfunction. The freezer is located in a secure room with swipe card access. The samples will be handled only by members of the research team.

Participants

Recruitment

38.1 Who will you be recruiting as participants for this study? Please select all that apply.*

- ☑ General public (over 18 years of age)
- ☐ Members of a collectivity
- ☐ People whose first language is not English
- ☐ People who are illiterate
- ☐ Pregnant women/human foetus
- ☐ Children
- ☐ People who are in a dependent or unequal relationship
- ☐ People who are highly dependent on medical care
- ☐ People with a cognitive impairment
- ☐ Aboriginal and/or Torres Strait Islander peoples
- ☐ People who may be involved in illegal activity
- ☐ UniSA staff
- ☐ UniSA students
- ☐ Not recruiting participants
- ☐ Other

38.2 Does the research involve issues likely to be considered significant to Indigenous peoples?*

- ○ Yes
- ◉ No
- ○ Not Applicable

Risk to Participants

Risk to Participants

51.1 Please select all that apply. This research project:*

- ☐ Has the potential to expose participants to potential civil, criminal or other proceedings
- ☐ Makes it possible for third parties to identify participants
- ☐ Involves a risk of physical injury
- ☑ Involves human exposure to ionising and/or non-ionising radiation (including X-ray)
- ☐ Involves exposure to disease or infection
- ☐ Involves pain or significant discomfort
- ☐ Involves psychological or emotional stress
- ☐ Involves sensitive personal information
- ☐ May expose participants to potential loss of professional reputation,market standing; employability
- ☐ May result in significant negative impact upon personal relations
- ☐ Offers an inducement which could be considered coercive
- ☐ Involves participation of people who legally cannot provide voluntary & informed consent
- ☐ None of the above

Ionising Radiation

You have indicated that this research involves human exposure to ionising and/or non-ionising radiation (including X-ray).

55.1 Is prior warning given, and instructions in relation to implications - in plain language - included in the informed consent materials)?*

- (•) Yes
- ( ) No

55.2 If appropriate, will potential participants be screened on the basis of complicating health factors, pregnancy and previous exposure?*

- (•) Yes
- ( ) No

55.3 Are the procedures to be conducted by experienced person(s)?*

- (•) Yes
- ( ) No

55.4 Are standard workplace health and safety procedures to be followed, and is appropriate workplace health and safety approval in place?*

- (•) Yes
- ( ) No

55.5 Will there be compliance with other standards? (Eg. UniSA Radiation Safety Committee Approval)*

- (•) Yes
- ( ) No

55.6 If required, are the persons conducting the procedures licensed and / or accredited?*

- (•) Yes
- ( ) No

55.7 Are the risks associated with the research easily minimised or managed?*

- (•) Yes
- ( ) No

55.7.1 Please provide details. *

Minimal radiation is emitted during DEXA scan but we will do only one measurement. All health and safety regulations will be followed an experienced person will conduct scans wearing radiation monitors and standing away from the scanner and monitor.

55.8 Why is it necessary to expose research participants to ionising and/or non-ionising radiation for this research?*

A DEXA scan is necessary to ascertain total lean body mass for the purpose of the caculation of glucose uptake.

55.9 Describe the radiation dose assessment and risk assessment obtained for this research.*

Total Body DEXA: 0.00037mSv.This poses a negligible risk for radiation exposure as natural background radiation in Australia is between 2 and 2.5mSv each year.

55.10 Has the dose assessment and risk assessment been verified by a medical physicist?*

- ( ) Yes
- (•) No

55.10.1 Provide an explanation.*

This has been completed in other studies using these types of DEXA scans. The OHSW radiation form has been completed and forwarded to Ian Furness

Ionising Radiation cont.

56.1 Is the use of radiation a novel use?*

- ( ) Yes
- (•) No

56.2 Will the radiation dose exceed the dose limits described in Table 1 of the ARPANSA Code?*

- ( ) Yes
- (•) No

56.3 Will the research participants include:*

- [ ] Pregnant women

- [x] Women of reproductive potential
- [ ] Neither

56.3.4 Will women of reproductive potential be given a recognised pregnancy test to exclude pregnancy?*

- (•) Yes
- ( ) No

56.4 What precautions will be taken to keep radiation dose and radiation exposure to a minimum?*

" As low as reasonably achievable" principle of radiation protection will be applied at all times. A Best Practice Quality Assurance program will be applied to minimise errors and avoid any repeated scans.

56.5 Is the site(s) where the radiation will be used actively involved in a relevant quality assurance program?*

- (•) Yes
- ( ) No

Whenever possible, in the case of research involving the radiation exposure of healthy research participants, participants should be selected who have not previously or are not currently exposed to radiation from research projects (Australian Radiation Protection and Nuclear Safety Agency Code 2.1.5(a)) ARPANSA Code

Right to Privacy

66.1 Does IS42 or the Commonwealth Privacy Act apply to the research (eg access to identified personal data held by third parties subject to privacy regimes)? Refer to the Privacy law.*

- ( ) Yes
- (•) No

Collection Method

Collection Method

67.1 Data collected for this research project will be collected directly from participants (e.g. they are completing a question about themselves, their thoughts, their opinions etc).*

- (•) Yes
- ( ) No

67.1.1 **Information which will be collected for this research project directly from the participant**

67.1.2 Describe the information that will be collected directly from participants. Be specific where appropriate.*

Name,contact information,demographics, height,weight,date of birth,medical history,medicine use

67.1.3 The information collected by the research team about participants will be in the following form(s). Please select all that apply.*

- [x] Individually identifiable
- [ ] Re-identifiable
- [ ] Non-identifiable

67.1.3.1 Give reasons why it is necessary to collect information in Individually identifiable or Re-identifiable form.*

Participants will be coming in multiple times so re-identification is necessary to add data. Informaiton will be coded and stored in a re-identifiable format so that individual data can be reviewed if necessary. Identification will be removed at project end.

67.2 Data collected for this research project will be collected from another person about the participant (e.g. asking participants' doctors about their patients medical history).*

- ( ) Yes
- (•) No

67.3 Will data collected for this research project involve the use or disclosure of information by an agency, authority or organization (other than UniSA)? (e.g. accessing participants' medical records)*

- ( ) Yes
- (•) No

67.4 Data collected for this research project will involve using information which you or your organisation collected previously for a purpose other than this research project?*

- ( ) Yes
- (•) No

67.5 Describe and justify how you will analyse the data collected from or about the participants.*

Data will be entered into a statistical analysis program forthe generation of descriptive statistics and correlation analysis.

67.6 Select all that applies to this project from the following:
Information collected for, used in, or generated by, this project.. *

- [x] Will not be used for any other purpose
- [ ] Will/may be used for another purpose by the researcher for which ethical approval will be sought
- [ ] Will establish a database/collection or register for future use (ethical approval will be sought)
- [ ] Will/may be made available to a 3rd party for subsequent use (ethical approval will be sought)
- [ ] Other

Participants Relationships

68.1 Is there an existing relationship or one likely to arise during the research, between the potential participants and any member of the research team or an organisation involved in the research?*

- ○ Yes
- ◉ No

68.2 Does the researcher / investigator have another role in relation to the participant?*

- ○ Yes
- ◉ No

68.3 Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations?*

- ○ Yes
- ◉ No

Consent

69.1 Will consent for participation in this research be sought from all participants? Refer to Chapter 2.2 of the National Statement.*

- ◉ Yes
- ○ No

69.1.2 Will there be participants who **have** capacity to give consent for themselves?*

- ◉ Yes
- ○ No

69.1.2.1 What mechanisms / assessments / tools are to be used, if any, to determine each of these participant's capacity to decide whether or not to participate?*

Participants will be given an information sheet outlining the study and a consent form indicating that they understand the information provided.

69.1.3 Will there be participants who **do not have** capacity to give consent for themselves?*

- ○ Yes
- ◉ No

Consent Process

70.1 Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project.*

Participants will be given a plain language statement describing the study and given the opportunity to discuss the research with independent persons (eg: friends, family,general practitioner). If interested, they will be asked to sign a consent form prior to starting this study.

70.2 If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision?*

- ○ Yes
- ◉ No

70.3 If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent?*

- ○ Yes
- ◉ No

70.4 Can individual participants be identifiable by other members of their group? (e.g. co-workers, focus group members etc.)*

- ○ Yes
- ◉ No

70.7 Will consent be specific or extended or unspecified? Refer to statements 2.2.14-2.2.18 of the National Statement.*

- ○ Specific
- ◉ Extended
- ○ Unspecific

70.7.1 Provide reasons why this form of consent has been chosen. *

We wish to retain blood samples for subsequent research.

Risks and Benefits

Risks and Benefits

Please note that when answering the following questions, only risks beyond those encountered in everyday life are relevant. Refer to Chapter 2.1 of the National Statement.

71.1 Are there any risks to participants as a result of participation in this research project (eg physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships)?*

- ○ Yes
- ◉ No

71.2 What expected benefits will this research have for the wider community?*

If a dietary pattern rich in nuts, legumes, whole grains and low fat dairy improves insulin sensitivity, this study will strongly support the recommendation of this diet for overweight and obese people with pre diabetes.
If a dietary pattern high in red, processed meat and refined grains affects negatively insulin sensitivity, this outcome will provide a convincing rationale in reducing the amount of intake of red, processed meat and refined grains for those with insulin resistance.
This study will provide clarification on dietary influences on insulin sensitivity and contribute to lowering risks of developing type 2 diabetes by changing the dietary patterns.

71.3 What expected benefits (if any) will this research have for participants?*

Even though participants will not have direct benefits throughout this research, it is expected that this study helps participants' understanding of how their diet will affect their health as well as gaining concepts of measuring of food quantities.This participation may provide them with the opportunity to exchage their routine diet.

71.4 Are there any other risks involved in this research? eg. to the research team, the organisation, others (eg physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships)*

- ○ Yes
- ◉ No

Risks and Benefits cont.

72.1 Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor(s)?*

- ○ Yes
- ◉ No

72.2 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, legal, social or financial well-being, or to their employability or professional relationships - or to their communities?*

- ○ Yes
- ◉ No

72.3 Describe how the members of the research team will monitor the conduct of the research. (e.g. Will regular meetings be held between researchers? Will student researchers be in regular contact with their supervisors? etc)*

Meeting will be held on a weekly basis with the primary supervisor and every other week with the co-supervisor.

72.4 **It is mandatory for researchers to report suspected cases of child abuse/neglect, domestic violence, bullying, illegal activities, use of illicit substances, abuse of elderly persons, professional negligence etc.**

72.4.1 Is it likely that this will be disclosed during the course of the project?*

- ○ Yes
- ◉ No

Researcher Training

73.1 List the relevant qualifications, experiences and /or skills of the research team which equip them to conduct this research.*

Both supervisors have extensive experiences in conducting clinical trials and dietary research which have been widely published in this field.

73.2 Do the researchers involved in this research project require any additional training in order to undertake this research?*

- ◉ Yes
- ○ No

73.2.1 Please describe the training required.*

1. Taking blood samples using a cannula
2. Lab analysis of blood samples

73.2.2 How and by whom will the training be provided?*

1. A venepuncture course has been taken. A supervisor and a medical practitioner Dr.Peter Clifton will provide additional training for the cannula method.
2. Laboratory persons will provide the training for lab analysis

73.2.3 How will the outcome of the training be evaluated?*

Dr.Clifton will assess proficiency in blood taking and use of the SphygmoCor; a coefficient of variation will be caculated for laboratory analysis.

73.2.4 Are there any potential safety implications for the researcher(s) (beyond those normally encountered in everyday life)?*

- ○ Yes
- ◉ No
- ○ Not Applicable

73.2.5 How will these will be addressed?*

n/a

Reporting of Results

74.1 Is it intended that results of the research that relate to a specific participant be reported to that participant?*

- ◉ Yes
- ○ No
- ○ Not Applicable

74.1.1 Specify in what form the results will be reported to participants.*

Individual letters

74.1.2 How will the results be communicated to participants? eg telephone call, individual letter, copy of publication, consultation with a medical practitioner or other.*

The results will be communicated by an individual letter.
Contents of an individual letter are followed.

1.A participant will obtain the whole results of this study as to how different types of dietary patterns affect insulin sensitivity in human.
2.A participant will be informed about his or her blood glucose level after a 75g OGTT.
If a participant is diagnosed with pre diabetes such as IGT (impaired glucose tolerance) or IFG (impaired fasting glucose) 2 hours after a 75g OGTT (oral glucose tolerance test), we will advise him or her to see a general practitioner for the purpose of lowering the risks of developing type 2 diabetes and its complications.
3.A participant will be given the information on pre diabetes such as impaired glucose tolerance (IGT) and impaired fasting glucose (IFG).
4.A participant will be provided with fasting blood glucose and insulin levels under fasting conditions.
5.A participant will be aware of the total lean body mass through the results of their DEXA scan.
6.A participant will have the results of lipid profiles such as LDL levels, TG levels, HDL levels etc.
7.A participant will receive the comments on their normal diet habits in an effort to lower risks of developing type 2 diabetes.

74.1.3 Who will be responsible for communicating the project results to participants?*

A PhD student

74.2 Is the research likely to produce information of personal significance to individual participants?*

- ○ Yes
- ◉ No

74.3 Will individual participant's results be recorded with their personal records?*

- ○ Yes
- ○ No
- ◉ Not Applicable

74.4 Is it intended that all or some of the results that relate to a specific participant be reported to anyone other than that participant?*

- ○ Yes
- ◉ No

74.5 Will research participants have the opportunity to receive a copy of your final report or summary of the findings if they wish?*

- ◉ Yes
- ○ No

74.5.1 How will you provide a copy of the final report or summary of the findings?*

Data will be de-identified and a summary report will be sent by mail.

Reporting of Results cont.

75.1 Is the research likely to reveal a significant risk to the health or well being of persons other than the participant (eg family members, colleagues)?*

- ○ Yes
- ◉ No

75.2 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?*

- ○ Yes
- ◉ No

75.3 How is it intended to disseminate the results of the research? Please select all that apply.*

- ☑ Thesis/dissertation
- ☑ Journal article/s
- ☐ Research paper
- ☑ Conference presentation
- ☐ Commissioned report
- ☐ Other

75.4 Will the confidentiality of participants and their data be protected in the dissemination of research results?*

- ◉ Yes
- ○ No
- ○ Not Applicable

75.4.1 Explain how confidentiality of participants and their data will be protected in the dissemination of research results.*

Data is de-identified;summary data only is presented

Attachments

Attachments

Note: You can upload additional documents by clicking on the "Add New Document" link. Types of documents which should be attached include Reference List/Bibliography, Information Sheet, Consent Form, Copy of Research Tools, Consent Form, Internet Questionnaire, Interview Questions, Focus Group Questions, Details of Observational Aspects, Details of Action Research Process, Insurance Confirmation, Organisational Approval, etc.

The Human Research Ethics Committee pays particular attention to Participant Information Sheets and consider them to be public documents.

HREC requires researchers to conform to the Participant Information Sheet Guidelines. Please refer to Chapter 2.2 (p20) of the National Statement.

A model consent form is available at Model Consent Form. Please ensure all irrelevant information is deleted as there are numerous notes to the researcher included in the model consent form to assist researchers to draft their form.

*

Description	Reference	Soft copy	Hard copy
1. Reference List	References (background).docx	✓	
2. Research Tools (or reasons as to why there aren't any)	research tool.docx	✓	
3. Participant Information Sheet (as applicable)	Information Sheet.docx	✓	
Consent Form (as applicable)	Consent Form.docx	✓	
Others (as applicable)	flyer.docx	✓	
Insurance Confirmation	Yoona Kim Insurance approval.docx	✓	
Q 15.3.1 participant information	15.3.1 answer.docx	✓	

Declaration

Declaration

The Primary Contact for this project is responsible for the application that is submitted and must be the one to agree to the following statement.

"On behalf of the research team for this project, I confirm that all members of the research have read the current NHMRC *National Statement on Ethical Conduct in Human Research*. The research team accepts responsibility for the ethical and appropriate conduct of the procedures detailed in this application, confirm that the research team will conduct this project in accordance with the principles described in the *National Statement*, and confirm that the research team will comply with any other condition laid down by the University of South Australia's Human Research Ethics Committee."*

☑ I Agree

Please click on the *Action* tab on the left hand side of the screen and click *Submit*.

Instructions

Instructions

Please click on the *Action* tab on the left hand side of the screen and click *Submit*.

Set Date

Approved Subject To Date

Please set the Approved Subject To date, click the Next green arrow, then click the Action tab and select *Set Date Approved Subject To*.

28/04/2014

Instructions

Please click the Action tab and select the appropriate date to set