ResearchMaster

Human Ethics Application

Application ID :	HEC16-022
Application Title :	A community based cross-sectional study on the association between Vitamin B12 status and sleep quality
Date of Submission :	24/03/2016
Primary Investigator :	Markandeya Jois; Chief Investigator
Other Investigators :	Jency Thomas; Associate Investigator
	Jessica Radcliffe; Associate Investigator
	Surafel Tegegne; Postgraduate Student

Administration

Important Information

Form Version: v1.1 | Last Updated: 18 February 2016

IMPORTANT INFORMATION FOR ALL APPLICANTS:

- La Trobe University abides by the National Statement on Ethical Conduct in Human Research (2007). The University Human Ethics Committee (UHEC) is a registered Human Research Ethics Committee (HREC) with the National Health and Medical Research Council (NHMRC). All Low Risk applications are reviewed by a College Human Ethics Sub-Committee (CHESC). The CHESC is composed of academics' from within the College.
- Research involving human participants (or their data or tissue) may not commence until written approval has been obtained from the UHEC or relevant CHESC.
- Most questions in this application are mandatory and must be completed before the application can be submitted. These questions are marked with a red asterisk (*).
- It is important that the application is written in lay language so that committee members not conversant in the discipline may fully comprehend and appreciate the proposal. Ensure all questions are appropriately answered in plain language with correct spelling and grammar.
- All applications must be sighted and approved by all members of the research team and any relevant parties. Applications will not be reviewed without appropriate authorisation.
- Please note that all applications must be submitted with the following supporting documentation, and you must use the templates provided on the La Trobe University Human Research Ethics website. *Additional required attachments will be identified in "Section 6 - Documents & Attachments".*
  - Participant Information Statement
  - Consent Form
  - Withdrawal of Consent Form
  - Other documents related to your project including advertisements, flyers, questionnaires, interview schedules etc.
- To avoid unnecessary delays, please ensure the application is submitted in full and all relevant guidelines have been followed.

THIS PROJECT MUST NOT COMMENCE WITHOUT PRIOR WRITTEN APPROVAL FROM THE UNIVERSITY HUMAN ETHICS COMMITTEE OR COLLEGE HUMAN ETHICS SUBCOMMITTEE
ONGOING APPROVAL REQUIRES SUBMISSION OF AN ANNUAL PROGRESS REPORT TO THE APPROVING COMMITTEE

Contact Details:

Human Ethics Approvals and Process
For assistance in completing the form, further information regarding clarification of any fields, specific content, or ethical conduct, please contact the relevant Ethics Officer for the committee reviewing your application.

- **Senior Human Ethics Officer**
  University Human Ethics Committee
  Phone: 9479 1443
  Email: humanethics@latrobe.edu.au
- **Human Ethics Officer**
  Arts, Social Sciences and Commerce
  College Human Ethics Sub-Committee
  Phone: 9479 6012
  Email: chesc.assc@latrobe.edu.au
- **Human Ethics Officer**
  Science, Health and Engineering
  College Human Ethics Sub-Committee
  Phone: 9479 3370
  Email: chesc.she@latrobe.edu.au

Technical help for eForm
For technical assistance including access and logging in to Research Master.

- **ResearchMaster Administrator**
  Phone: 9479 6843
  Email: ResearchMasterAdmin@latrobe.edu.au

Help and Resources

- La Trobe University Human Research Ethics website
- NHMRC: National Statement on Ethical Conduct in Human Research
- NHMRC: Australian Code for the Responsible Conduct of Research

Section 1 - General Details

Core Project Details

*Ethics Category**

Human

1.1. **Project Title***

A community based cross-sectional study on the association between Vitamin B12 status and sleep quality

1.2. **Primary Academic Organisational Unit (AOU)***

Dietetics & Nutrition

1.3. **Type of research project to be conducted***

- ○ Research by Academic Staff Member
- ○ Contract Research
- ○ Undergraduate Research
- ◉ Postgraduate Research

1.4. **Project Summary**
*Provide a brief summary in lay terms of the research project as a whole. Outline the broad aims, background, design and approach of the project, with particular reference to who the participants will be and what they will be asked to do (maximum 100 words).**

This proposed study aims to investigate the association between Vitamin B12 status and sleep quality in healthy people aged between 18-65 years in a community based set-up in Melbourne. With the aid of one week food diary, this study will also aim to interrogate if consuming different variety of food affects sleep quality. To date although studies have been conducted on sleep quality, very few studies have looked at the effect of vitamin B12 on sleep quality. The significance of this study is also that this study will be a community based and not in sleep clinics. Sleep clinics could potentially affect sleep and confound the results.

1.5. **Period for which ethical approval is sought***

- ◉ Immediately upon receiving ethical approval
- ○ Other date

1.6. **Expected date for conclusion of project***

29/12/2017

Investigators

1.7. **Will any students be involved in the conduct of this project?**
This includes both student projects, where research is being undertaken for the degree in which the student is enrolled, and staff projects, where research is being undertaken by an Academic Staff Member that involves a student(s) carrying out some part of the project.*

- ◉ Yes
- ○ No

If yes, please include details of students in the table below and assign them the role **Postgraduate Student** or **Undergraduate Student** as applicable. *Do not assign an investigator role to a student researcher.*
You must also provide details of the role of the student in the project and detail their related experience.

1.8. **Will any personnel who are not current staff members or students of La Trobe University be involved in the conduct of this project? ***

- ○ Yes
- ◉ No

1.9. **List all investigators associated with this project.**
Important: For the purposes of this application, the nominated Chief Investigator MUST be a staff member of La Trobe University (not any affiliated institute).
You must assign only ONE person in the Chief Investigator role and this person MUST be listed as the Primary Contact on your application.
For student projects, the Chief Investigator/Primary Contact MUST be the supervisor, not the student.*

1	**System Information**	
	Staff / Student ID Number	00332318
	Surname	Jois
	Given Name	Markandeya
	Full Name	Markandeya Jois
	College / Institute / Department	Dept AP & SS - Agricultural Sciences 1160
	Personnel Type	Internal
	Email Address	M.Jois@latrobe.edu.au
	Application Information	
	Position / Role in project	Chief Investigator
	Primary contact for application? *Students cannot be the primary contact for an ethics*	Yes

	application.	
	Phone number	9479 2172
	Academic Title / Qualification If student, provide details on level and course of study (PhD, Masters, Honours, etc.)	BSc.Vet(Hons), PhD
	Experience and/or skills relevant to the project.	Over 20 years experience in nutrition related research. Experience in clinical trial design.
2	**System Information**	
	Staff / Student ID Number	00083115
	Surname	Thomas
	Given Name	Jency
	Full Name	Jency Thomas
	College / Institute / Department	Dept PA & M - Humn Bio Sciences 1229
	Personnel Type	Internal
	Email Address	J.Thomas@latrobe.edu.au
	Application Information	
	Position / Role in project	Associate Investigator
	Primary contact for application? *Students cannot be the primary contact for an ethics application.*	No
	Phone number	9479 5755
	Academic Title / Qualification If student, provide details on level and course of study (PhD, Masters, Honours, etc.)	PhD
	Experience and/or skills relevant to the project.	Experience in nutrition research using animal models and clinical trials
3	**System Information**	
	Staff / Student ID Number	00059870
	Surname	Radcliffe
	Given Name	Jessica
	Full Name	Jessica Radcliffe
	College / Institute / Department	Dietetics & Nutrition
	Personnel Type	Internal
	Email Address	J.Radcliffe@latrobe.edu.au
	Application Information	
	Position / Role in project	Associate Investigator
	Primary contact for application? *Students cannot be the primary contact for an ethics application.*	No
	Phone number	9479 1504
	Academic Title / Qualification If student, provide details on level and course of study (PhD, Masters, Honours, etc.)	BNutrSc(Hons) PhD
	Experience and/or skills relevant to the project.	Experience in clinical trial design and nutrition research.
4	**System Information**	
	Staff / Student ID Number	17530802
	Surname	Tegegne
	Given Name	Surafel
	Full Name	Surafel Tegegne
	College / Institute / Department	Physiology Anatomy & Microbiology
	Personnel Type	Student
	Email Address	stegegne@students.latrobe.edu.au
	Application Information	
	Position / Role in project	Postgraduate Student

	Primary contact for application? *Students cannot be the primary contact for an ethics application.*	No
	Phone number	0455306100
	Academic Title / Qualification If student, provide details on level and course of study (PhD, Masters, Honours, etc.)	MSc
	Experience and/or skills relevant to the project.	4.5 years in the field of research including; 2 years at masters level and 2.5 years at PhD level. Student has completed research projects on the topic in an animal model.

Project Funding

1.10. **How will this project be funded?***

- ☐ External Grant
- ☐ La Trobe Internal Grant, e.g. RFA Funding
- ☐ Sponsored / Contract Research
- ☑ Unfunded (Supported by Department or Organisation)

1.11. **Have you submitted an online Project Request application through ResearchMaster that is linked to this project?** E.g. RAS or RFA funding application*

- ○ Yes
- ◉ No

Note: All funded research conducted at La Trobe University requires approval through the RAS. Please ensure a RAS is completed through the projects module as soon as possible.

External Involvement

1.12. **Is the research a collaborative effort with another organisation?***

- ○ Yes
- ◉ No

1.13. **Will any part of the research be conducted in a location other than a La Trobe University campus?** (e.g. clinic, school, hospital, support centre, etc.)*

- ○ Yes
- ◉ No

1.14. **Does this research require formal approval or permission to be obtained by an external HREC, institution or authority?** (e.g. Department of Education and Training)*

- ○ Yes
- ◉ No

Section 2 - Project Overview

Project Description

2.1. **Aims**

*Provide a concise statement of the aims and significance of the project in plain language.**

This proposed study aims to investigate the association between Vitamin B12 status and sleep quality in healthy people aged between 18-65 years in a community based set-up in Melbourne. With the aid of one week food diary, this study will also aim to interrogate if consuming different variety of food affects sleep quality.
To date although studies have been conducted on sleep quality very few studies have looked at the effect of vitamin B12 on sleep quality. The significance of this study is also that this study will be a community based and not in sleep clinics. Sleep clinics could potentially affect sleep and bais the results.

2.2. **Background and Rationale**

*Briefly describe the relevant background and rationale for the project in plain language. Outline the relevant research and literature review, and provide a justification as to why this research should proceed.**

Vitamin B12 (B12), is a water-soluble molecule that functions as an essential coenzyme for two enzymes in the human body. They are the cytoplasmic methionine synthase, which catalyzes methylation of homocysteine to methionine; and methylmalonyl-CoA mutase, which catalyzes the conversion of methylmalonyl-CoA to succinyl-CoA in the mitochondria. Whilst there are some plant-based sources of vitamin B12, such as certain algae and plants exposed to bacterial action or contaminated by soil or insects, human beings mainly obtain their vitamin B12 from animal food sources.
Scientists defined sleep as a period of unconsciousness during which brain remains highly active cycling through five distinctive phases to make sure the whole body and mind get enough rest and wake up energetic next day. It can be affected by numerous factors including nutrition. Previously, studies have shown that there is direct or indirect association between sleep and B12. From a study in Mysore city in south India, it has been reported by Zadeh and Begum (2011) that as compared to normal sleepers people with insomnia consume significantly lesser quantities of energy, carbohydrates, folic acid, and B12. In this study, questionnaire which used Insomnia Screening Index as well as a three days food diary of participants was used to come to the conclusion. Beydoun, Gamaldo et al. (2014), on the other hand, from a national survey observed an independent inverse association between serum B12 and sleep duration among US adults. Elevated plasma homocysteine level, which is a common indicator of B12 deficiency, was reported by a study involving shift bus drivers who have disrupted circadian rhythm due to their irregular shift schedules (Martins, D Almeida et al. 2003).
However, both sleep and B12 status can highly be affected by social, economic, religious, genetic, environmental and other factors. If we take sleep quality and duration, it is not uncommon to find discrepancy in sleep pattern of people from different background depending on their work load, stress levels in their life, sleeping situations and many other reasons. B12 status is also very dependent on many factors such as socio-economic reasons and age which is known to be cause of malabsorption.
Moreover, most sleep studies are conducted in a sleep hospital set-up which does not mimic the actual sleep environment and can highly interrupt sleep quality and duration of participants and, as a result, confounds the outcomes of studies. The other commonly used method to conduct sleep study is using sleep questionnaires which can produce less reliable information simply because of human error or lack of precision as respondents can only have rough estimate and not actual data on their own sleep pattern.
In this trial, however, we aim at using activity sensors that the participants will be wearing as a watch on their wrist to monitor their sleep quality and duration. This will help us collect the actual sleep pattern while they sleep at the place where they normally sleep without affecting their daily activity. Besides, we will collect blood samples to quantify participants¿ nutritional bio-markers in addition to food diary that the participants will be asked to keep for at least 7 days. Also, body composition data will be collected by using Dual-energy X-ray Absorptiometry (DXA) scan.
Therefore, it is relevant to explore the link between sleep and B12 status in Australian population and it is logical to expect different outcomes because of the nature of the focuses areas.

2.3. **Detailed Procedures**
*Include all details relating to the methodology, recruitment strategy, data collection techniques, the tasks participants will be asked to do, an estimate of the time commitment involved, and methods of data analysis.**

Recruitment strategy:
Flyers and posters will be distributed in La Trobe University, Bundoora campus and outside to announce and recruit volunteers between 18 and 65 years old. Social media such as face book will be utilized to announce the trial. Clinical Trials Connect Database will be utilized to recruit with an in built screening system.
People who are highly dependent on medical care, people with a cognitive impairment, intellectual disability or mental illness, people diagnosed with sleep apnea and are taking sleep medication will not be included in this study.
Data collection techniques:
Short questionnaire will be collected to get background information about participants and about their sleep pattern as well as their plane of nutrition. Besides, sleep data will be collected using activity monitors which participants will be wearing on their wrist for seven consecutive days. Additionally, while the participants wear the activity monitors, they will be requested to write their food diary. Moreover, body composition and other relevant body measurements will be taken using DEXA.
The tasks participants will be asked to do:
The participants will have two visits. The first visit is to submit the signed PIS/CF and collect an activity monitor. In addition, they will be asked to complete a short questionnaire, collect their food diary, have a DEXA scan and a blood sample will be taken. The second visit, after 7 days of data collection, will be to collect the activity monitor as well as the food diary. An estimate of the time commitment involved will be approximately ten days.
Methods of sample and data analysis:
Blood samples will be analysed for B12, homocysteine, methylmalonic acid (MMA) and other relevant nutritional bio-markers.
Data from activity monitor will be copied to a computer with ACTi graph software. Questionnaire and food diary data will also be entered to SPSS and analysed.

2.3.a. *Use this textbox if additional room is required for Detailed Procedures.*

This question is not answered.

Type of Project

2.4. **Does the research only include the collection of anonymous and non-sensitive data (e.g. online survey, observational data) that poses no foreseeable risks or discomfort to participants?** In this case, any foreseeable risk must be no more than inconvenience.
*Only answer 'Yes' if there will be no other forms of data will be used throughout this project.**

- ○ Yes
- ◉ No

2.5. **Does the research only include the use of non-identifiable and non-sensitive data from an existing database? (e.g., data mining).**
Such data should pose no foreseeable risks or discomfort to individuals whose information is contained in the database, or to individuals/organisations responsible for the database.
*Only answer 'Yes' if there will be no other forms of data used throughout this project.**

- ○ Yes
- ◉ No

2.6. **Is this project part of a larger project?***

- ○ Yes
- ◉ No

Target Population

This section contains questions specifically relating to the National Statement on Ethical Conduct in Human Research, Section 4: Ethical Considerations Specific to Participants. Please click the Help icons next to the questions for a link to the relevant section of the Statement.

2.7. **Does the research involve pregnant women and/or the human foetus?***

- ○ Yes
- ◉ No

2.8. **Does the research involve children and/or young people under the age of 18 years?***

- ○ Yes
- ◉ No

2.9. **Will the research potentially involve any participants in dependent or unequal relationships with any of the members of the research team or people involved in recruitment?**
For example, teacher/student, doctor/patient, student/lecturer, client/counsellor, employer/employee. Such relationships may compromise a participant's ability to give consent which is free from any form of pressure, real or implied. *

- ◉ Yes
- ○ No

2.9.a. If yes, explain the relationship and the measures to be taken to ensure that participation is voluntary and not influenced by the relationship in any way.*

It is possible that amongst all investigators there are participants recruited who are in a dependent relationship such as student/lecturer relationship, however, the investigators recruiting for this study are professionals with many years of experience in professional practice including clinical research involvement.
Recruitment will be done through flyers in which Mr Surafel Tegegne (PhD candidate) is the contact person. The list of persons enquiring to participate in the study will be screened by the research team and any potential conflict of interest will be declared in a signed declaration form and kept along with the consent forms.

2.10. **Does the research involve people highly dependent on medical care who may be unable to give consent?***

- ○ Yes
- ◉ No

2.11. **Does the research involve people with a cognitive impairment, intellectual disability or mental illness?***

- ○ Yes
- ◉ No

2.12. **Does the research involve people who may be involved in illegal activities?***

- ○ Yes
- ◉ No

2.13. **Does the research involve Aboriginal and/or Torres Strait Islander peoples?***

- ○ Yes
- ◉ No

2.14. **Does the research involve people in other countries?***

- ○ Yes
- ◉ No

Research Methodology

2.15. **Does the research involve interventions, therapies or innovations (either non-clinical or clinical)?***

- ○ Yes
- ◉ No

2.16. **Does the research involve the collection of human biospecimens (i.e. tissue or fluid samples, etc.) directly from participants?***

- (●) Yes
- ( ) No

2.16.a. Specify what will be sampled, and how samples will be taken. *Include the frequency and volume of all samples.**

Blood will be collected once only by venepuncture. Volume collected will be maximum of 40ml.

2.16.b. How will samples be stored?*

Samples stored in -80 degree freezer after processing samples for serum/plasma.

2.16.c. How will samples be disposed of?*

Samples will be disposed of using the Biological waste service at LTU.

2.16.d. Specify who will take samples and their qualifications for doing so.
Attach any related certifications in "Section 6 - Documents & Attachments".
*

Blood samples will be taken by investigators trained in phlebotomy. A minimum qualification of a short course in venepuncture (RMIT). One of the researchers (Dr. Jessica Radclife) has venepuncture training certificate since 2013 from RMIT University and has been practicing blood samples collection in several human trials. Additionally, the other researcher (Surafel Tegegne) has just completed the venepuncture training provided on 29/04/2016 in RMIT University and waiting for the certificate.

2.17. **Will the research involve the use of human biospecimens (i.e. tissue or fluid samples, etc.) which will be provided by an institution or organisation?***

- ( ) Yes
- (●) No

2.18. **Does the project involve human genetic research?***

- ( ) Yes
- (●) No

2.19. **Will the research discover or generate health information of potential importance to the future of participants, their blood relatives or their community?***

- (●) Yes
- ( ) No

2.19.a. Describe your **ethically defensible plan** to either disclose or withhold the information.*

The participants will receive a final report with all results. At the time of disseminating results, a summary will be included that may outline any potential health risks, for example B12 deficiency, and recommend the participant raise this with their GP.
a. Participant information statement explaining the nature of the study will be given to participants and consent forms are prepared to be signed by researchers and participants before collecting any blood samples. Participation will entirely be voluntary.
b. In this study the only bio-specimen to be collected is blood and the information that will be generated from blood samples is nutritional bio-markers (particularly vitamin B12 deficiency indicators). Therefore, it possible that the research can generate information that may be important for health of the donors and blood relatives or their community.
c. Individual results are coded and will only be re-identified at the final stage if participants chose to receive their individual nutritional bio-marker analysis and feedback after conclusion of the study in the consent form.
d. Resource requirements and infrastructure in place to support the return of information of the kind referred to in b and c in ethically appropriate manner. Specimens will be collected at La Trobe University and all samples and results will be coded. Results will be documented with the chief investigator of this project and will be returned to the participants if they wish to know their results, however if there are any concerns regarding the B12 results of any participant i.e. results showing high or low readings then the chief investigator will contact the concerned participant and ask them to consult their GP or repeat the test as directed by the GP.
e. Participants will be given a choice to receive such information when they sign the consent form.
f. To identify and contact participants, their coded data can be re-identified to match with names.
g. To make sure that no sampling and coding error happens, careful records and backups will be kept using both hard and soft copies.
h. The findings of specific tests being undertaken as part of the research will be produced or validated in an accredited lab.
i. All investigators are responsible for any subsequent care requirements.

2.20. **Does the research involve the use of ionising radiation?***

- (●) Yes
- ( ) No

You must include a risk statement in the Participant Information Statement. The medical physicist who reviewed your application will provide you with this.

2.20.a. **Has an approved medical physicist assessed the application and written a report on the radiation doses and risks involved?***

- (●) Yes
- ( ) No

Please attach the medical physicists letter in "Section 6 - Documents & Attachments".

2.20.b. Describe all procedures involving radiation. Include the type of exam (e.g. CT, DEXA etc.), the number and frequency of investigations (e.g. 2 times, every 6 weeks), the effective dose per investigation (mSv) and the institution where the procedure will occur.*

This research involves exposure to a very small amount of radiation from DEXA scans that would bot normally be received. These scans will be conducted at La Trobe University Bundoora campus. One scan per participant will give radiation less than 0.01 mSv, which is less than the natural background radiation we receive annually (2 mSv).

Privacy & Disclosure

2.21. **Will participants be photographed, video recorded or audio recorded at any time?** *

- ☐ Photographed
- ☐ Video Recorded
- ☐ Audio Recorded
- ☑ N/A

2.22. **Will any form of deception, concealment or covert observation be used at any time?***

- ○ Yes
- ◉ No

2.23. **Is it possible that a conflict of interest issue could arise in relation to this research?**
This includes any circumstance which might represent a **perceived, potential or actual** conflict of interest, and may relate to any type of financial, personal or other affiliated benefit for the researchers or organisations involved in this project.*

- ○ Yes
- ◉ No

2.24. **Will participants be informed of funding source(s)?***

- ◉ Yes
- ○ No

2.24.a. If yes, explain how participants will be informed.*

This is a University funded research, as part of a PhD research project. This information will be included on the PIS.

2.25. **Does the research involve the collection, use or disclosure of identifiable or re-identifiable information from sources other than the individual(s) to whom the information relates, without the consent of those individuals?**
Note that access to identifiable records for the purpose of extracting non-identifiable data constitutes 'use' and 'disclosure' of identifiable data even if such data will not be 'collected'. *

- ○ Yes
- ◉ No

Section 3 - Participants

Participant Details

3.1. **Total number of participants required for project***

111

3.2. **Is there likely to be an imbalance between the number of males and females participating?***

- ○ Yes
- ◉ No

3.3. **Age range of all participants***

Participants will be 18-65 years of age.

3.4. **Rationale for total participant number**
*Outline the analysis undertaken to determine the need for the specific number of participants for this study, explaining how this sample size will allow the aims of the study to be achieved.**

Samples size calculation for this study has been made by La Trobe University statistician Dr Leila Karimi. Based on previous study and using G power, number of participants has been determined to be 111 to provide 95% power. This allows 10% dropout of participants to see correlation.

3.5. **Will participants be split into two or more groups for the purpose of conducting the research?***

- ○ Yes
- ◉ No

Participant Selection

3.6. **What are the inclusion and exclusion criteria for your study? Please also include justification for each criterion.***

Inclusion:
Anyone aged between 18-65 can participate in the trial - this age range enables broader recruitment but also avoids recruiting an age group with an increased chance of poor health and fragility. People who take B12 supplements will not be excluded but supplement data will be collected.
Exclusion:
Those who are highly dependent on medical care, people with a cognitive impairment, intellectual disability or mental illness or who are non-English speaking (to ensure ethical consent)
People diagnosed with an active malignancy, chronic heart failure, chronic inflammatory disease will be excluded due to increased risk and likelihood of medical issues which may affect sleep quality (possibility of increasing confounding factors) and also those who are currently breastfeeding or pregnant (to reduce risk to the unborn or young child with DXA), currently participating in an intervention targeting sleep (to reduce confounding factors), and those unable to attend the appointment (data collection requires physical presence) will be excluded from participating.
People diagnosed with sleep apnoea and who are taking sleep or depression medication will be excluded (possible confounding factors).

3.7. **Does the research involve a participant population whose principal language is not English?***

- ○ Yes
- ◉ No

3.8. **Are any of the participants La Trobe University students?***

- ◉ Yes
- ○ No

3.8.a. Is yes, explain the steps taken by the investigators to ensure that the student's participation is purely voluntary.*

Participants and researchers are required to sign a consent form which states that all participants are volunteers. The participants are also informed that withdrawal at any time is possible.

Recruitment

3.9. **Where will participants be approached or recruited?**
Note: Where participants are recruited from schools, hospitals, prisons or other institutions, permission/approval from the institution or appropriate authority must be sought *(see "Section 1 - External Involvement").**

Recruitment methods:
- Advertisement email will be sent to all La Trobe University staff email (Appendix A). Approval will be sought by the Internal Communications Manager and heads of Departments prior to sending this email.
- The study will be advertised on the Clinical Trials Connect (CTC) website and also on the CTC Facebook page and also on TV channels as organised by CTC (Appendix B).
- La Trobe University Twitter page administrators will be contacted and an advert listed with a link to the CTC website (Appendix C), approved by Online Community Manager.
- Flyers will be placed on University campus noticeboards (Appendix D).
- Distribution of the attached mailbox drop-off flyer in local suburbs such as Bundoora, Heidelberg and Reservoir (Appendix E).
- Distribute the study advertisement flyer (Appendix D) to local businesses with prior agreement by email request (Appendix F).
- Display details of our study on the La Trobe University Food For Life website (Appendix G).
- Advertise through UniNews online communication (Appendix H). We will submit for a single advertisement, but will re-submit the same advert should further recruitment be necessary.

3.10. **How will potential participants be approached and informed about the research and how will they notify the investigators of their interest in participating?**
Attach the proposed Participant Information Statement and any flyers or other advertising material to be used in the research in "Section 6 - Documents & Attachments". *

Potential participants will be contacted via their email, phone and other means of contact they provide when they respond to recruitment methods listed above.

3.11. **Will you use an existing database to obtain names and contact details of potential participants? ***

- ○ Yes
- ◉ No

3.12. **Will any personnel other than the members of the research team listed in "Section 1 - Investigators" above (e.g. independent contractors), be involved in the recruitment of participants, or approach potential participants to seek their participation?***

- (●) Yes
- ( ) No

3.12.a. If yes, provide details of the involvement of these individuals and specify how you will ensure they conduct the research in accordance with the requirements of the National Statement.*

The study will be advertised on the Clinical Trials Connect (CTC) website and also on the CTC Facebook page and also on TV channels as organised by CTC and through La Trobe University Twitter page. These avenues of recruitment entail people already registered on the CTC mailing list or affiliated with the LTU Facebook and Twitter pages to receive information about our trial. We will not be given those potential participants details, it will be up to the potential participant to contact us.

3.13. **Will participants be offered any type of financial incentive or other compensation?***

- (●) Yes
- ( ) No

3.13.a. If yes, provide details of any types of reward or compensation that will be offered to participants.*

A $30 cash will be provided to participants at their second visit to compensate their transport expenses.

Besides, we will provide them with information on their health including a DEXA body composition report - valued at ~$120; their blood nutritional bio-markers profile as well as a report on their nutrient intakes and whether they meet recommended daily intakes.

Informed Consent

3.14. **How will consent be obtained?***

- (●) Participants will be required to sign an informed consent form
- ( ) Consent will be implied e.g. by return of completed questionnaire
- ( ) Verbal consent will be obtained and recorded (audio, visual or electronic)
- ( ) Other
- ( ) Consent will not be obtained

If consent will be obtained:

3.14.a. Specify the type of consent that will be obtained:

- (●) Specific: limited to the specific project under consideration
- ( ) Extended: given for the use of data or tissue in future closely related research projects
- ( ) Unspecified: given for the use of data or tissue in any future research

3.14.b. Explain in detail how consent will be obtained and recorded.
Attach the proposed Consent Form in "Section 6 - Documents & Attachments".
*

At the first visit participants will be explained what the project is about and its significance.Obtaining consent from the participants would involve provision to the participants at their level of comprehension of information about the purpose, methods, demands, inconvenience, discomforts and possible outcomes of the research. A participant would be considered competent to given consent provided they are able to understand and have complete understanding of the project before giving voluntary consent. Participants will be given a Participant Information Statement and as much time as they require to consider whether to participate or not. Eligible participants will be then given a consent form to sign which will be stored in a file and locked up in a safe cabinate of the chief investigator of this project.

3.15. **Will there be any participants who do not have the capacity to give voluntary and informed consent?***

- ( ) Yes
- (●) No

3.16. **Will potential participants be given time to consider and discuss their involvement in the project with others (e.g. family) before being requested to provide consent? ***

- (●) Yes
- ( ) No

3.17. **How will competence to give consent be determined and who will make this determination?**
Describe procedures to determine competence to give consent.*

The participants are above 18 years old and healthy and are considered to be competent to give consent. However, depending on the context, the chief investigator will discuss the details of the project and its potential outcome with the participant ahead of signing the consent.Obtaining consent from the participants would also involve provision to the participants at their level of comprehension of information about the purpose, methods, demands, inconvenience, discomforts and possible outcomes of the research. A participant would be considered competent to given consent provided they are able to understand and have complete understanding of the project before giving voluntary consent.

3.18. **Will the participant's capacity to provide voluntary and informed consent be reviewed while research is in progress?***

- ○ Yes
- ◉ No

3.18.a. If no, provide reasons why this is not necessary for this research.*

We will make sure all participants are well aware of the trail before they start their participation and signing the consent form.

3.19. **Will participants be informed of their right to withdraw from participating in the study at any time?***

- ◉ Yes
- ○ No

3.19.a. If yes, describe how participants will be able to withdraw their consent to participate in the study.
Attach the proposed Withdrawal of Consent Form in "Section 6 - Documents & Attachments".
*

when explaining the details of this project at the first visit, they will be given an option to choose not to participate.

3.20. **Will the participants be informed of their right to withdraw their consent for their data to be used in the study, including time limitations to this?***

- ◉ Yes
- ○ No

3.20.a. If yes, describe how participants will be able to withdraw their consent for their data to be used in the study and detail any restrictions to this.*

While signing the consent form to participate in this study the participant will be given an option that they could withdraw from the study at any time without giving reason. If they choose to withdraw from the study at anytime they have the option of withdrawing all data relating to them and any samples collected from them will be destroyed. Their confidentiality will be maintained at all times. Participants have a right to demand that data arising from your participation are not used in the research projected provided that this right is exercised within four weeks of the completion of you participation in the project.

Section 4 - Risks

Risk & Safety

You must consider any and all risks (no matter how unlikely), in both the short and long term.

Psychological Risks

4.1. **Is there any risk of psychological, emotional or social harm to the participants or research team?**
This includes any circumstance which may be experienced as stressful, noxious, aversive or unpleasant during or after the research procedures.*

- ◉ Yes
- ○ No

4.1.a. Explain the type and degree of risks or potential harm to any individuals.*

There might be a very small chance of emotional consequence from the outcomes of Center for Epidemiologic Studies Depression Scale (CESD). It is a tool to measure symptoms of depression and can tell whether a participant is suffering from a depressive disorder or not.

4.1.b. Provide details of appropriate strategies to be employed to minimise this (for example, making available a counselling service).*

Free counselling service will be offered as support for any emotional distress negative results may cause. Also, there will be a point of referral should further counselling be sought.

4.2. **Is there any risk of participants being asked to perform any acts or make any statements which might diminish their self-esteem or cause them to experience embarrassment or regret?***

- ○ Yes
- ◉ No

Legal Risks

4.3. **Is there any risk of legal harm or liability to the participants, the research team, and/or the University?***

- ○ Yes
- ◉ No

Financial Risks

4.4. **Is there any risk of financial harm or liability to the participants, the research team, and/or the University?***

- ○ Yes
- ◉ No

Physical Risks and Safety

4.5. **Does the research involve any potential physical risks or harm to the participants and/or researchers? ***

- ◉ Yes
- ○ No

4.5.a. Explain the type and degree of risks or potential harm to any individuals.*

Blood sampling is a common procedure in any medical facility. When blood is taken there is a possibility of minimal discomfort and/or bruising, infection, excess bleeding, clotting or fainting. As a protective measure, participants will be advised in the PIS/CF on preventive strategies to minimise risk of these symptoms.
Full body DEXA scans impose minimal risk. This research involves exposure to a very small amount of radiation from DEXA scans that would normally not be received.

4.5.b. How will the risk(s) be minimised, and how will these risks be managed if an adverse event where to happen?*

Venepuncture: Trained phlebotomists will take blood samples from participants. Prevention and management advice of venepuncture complications will be instructed to the participants and includes: Not to use the affected arm for heavy weights; Application of pressure to puncture site if bleeding commences; Removal of swab within 24 hours or prior if it becomes wet; Seek medical attention if additional swelling or redness develops around puncture site.
DXA: This research study involves exposure to a very small amount of radiation from a DXA scan than you would not normally receive. As part of everyday living, we are exposed to naturally occurring background radiation and receive a dose of about 2 millisieverts (mSv) each year. The effective dose participants will receive from this DXA scan, on the other hand, is approximately 0.01 mSv. At these dose levels, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The risk is believed to be minimal. These numbers are based on radiation safety approval report prepared by consultant. Please see the attachment.
If you have been involved in any other research studies that involve radiation, please inform us.
Please keep this Patient Information and Consent Form that includes information about your exposure to radiation in this study for at least five years.
You will be required to provide this information to researchers of any future research studies involving exposure to radiation.

4.5.c. Indicate the first aid procedures that will be available and clarify who will administer these procedures. *If the research involves possible physical risk, a first aid person must be on call.*
Attach evidence of certification/qualification of persons administering first aid in "Section 6 - Documents & Attachments".
*

The investigators are trained to give first aid services, should a researcher not holding current first aid certificate, a first aid person will be on call during the time of the appointment.

4.6. **Does the research involve any special equipment, apparatus, plant or machinery?***

- ◉ Yes
- ○ No

4.6.a. **Provide full details of the equipment, venue and procedures to be used, as well as all safety and protective measures to be in place.**
Attach evidence that your equipment has passed relevant electrical or other safety assessment or a statement of safety from the La Trobe University Occupational Health and Safety Office in "Section 6 - Documents & Attachments".
*

A hand watch size Activity monitors will be distributed to participants which they will be wearing on their wrist for the entire period of the trial. The activity monitor presents only a small risk, likely of scratch if worn incorrectly.
DXA body scanning equipment which is situated in LIMS2, La Trobe University will be operated by a trained person to quantify participants body composition. The equipment is a Hologic, Discovery model and was recently calibrated by the technician in mid 2015.

Potential Benefits

4.7. **Detail any and all potential benefits this research project may provide to the individual participants.***

It cannot be guaranteed or promised that participants will receive any benefits from this research, however, possible benefits may include awareness of vitamin b12 deficiency and other health factors such as body composition. Other benefits include the opportunity to contribute to medical research and improve the health of other Australians with sleep quality issues.

4.8. **Detail any and all potential benefits this research project may provide to the community and humanity in general.***

This research will ideally result in provision of evidence that Vitamin B12 is related to sleep quality. Additionally, this research will potentially assist in support for a well balanced diet in achieving RDIs for vitamins, such as B12.

Section 5 - Data & Records

Data Collection

5.1. **Indicate the type of information that will be collected: ***

- [x] Personal information
- [x] Sensitive information
- [x] Health information
- [ ] Other

5.2. **Indicate which of the following will be collected during the course of the research:***

- [x] Written questionnaires/survey responses
- [ ] Individual interview responses/notes
- [ ] Archival data
- [ ] Other data
- [ ] Group interview or focus group responses/notes
- [x] Participant observations
- [ ] Direct electronic data entry
- [x] Blood or tissue samples
- [x] Physiological measures
- [ ] Biomechanical measures
- [ ] Accessed health/medical records or data
- [ ] Accessed student academic records or data

Attach copies of all proposed questionnaires (including those that are published or commercially available) in "Section 6 - Documents & Attachments".

5.3. **Will any personnel other than the members of the research team listed in "Section 1 - Investigators" (e.g. independent contractors), be involved in the collection of any data?** *

- ○ Yes
- ◉ No

5.4. **Will any personnel other than the members of the research team listed in "Section 1 - Investigators" (e.g. independent contractors), have access to any data collected?** *

- ○ Yes
- ◉ No

5.5. **Where will the data be collected?** Give details for all types of data collected and all locations.*

All data will be collected at La Trobe University precinct. LIMS2, Room 308 for completion of the questionnaire and blood collection and Room 309 for DEXA scan.

5.6. **How will the data be analysed?** Give details for all types of data collected.*

Following data will be analysed using SPSS, Actilife, and Graphpad software;
1) Blood levels of vitamin B12 and other nutritional bio-markers data.
2) Data on Sleep Quality Related Measure.
3) Centre for Epidemiological Depression Scale (CEDS).
4) Food dairy.
5) Activity monitors (includes physical activity, sleep quality).

5.7. **Indicate the projects the data collected in this project is intended to be used for.** *This includes all data, tissues, specimens and other samples.**

- ◉ This project only
- ○ Future projects specifically related to this project
- ○ Any future research

Data Storage & Security

During the course of the study:

5.8. **Indicate how the data, materials and records will be kept:***

- ○ All data will be entirely non-identifiable
- ◉ Data may be potentially identifiable (e.g. coded)
- ○ Data will be wholly identifiable

5.9. **Indicate how the security of project documentation will be maintained.**
Project documentation should be stored in secure, lockable locations, preferably on campus. Computer files should be password protected.
The Research Data File Storage - http://www.latrobe.edu.au/research-infrastructure/digital-research/data/data-storage*

- [ ] Use of the Research Data File Storage
- [x] Codes and data kept separately
- [x] Lockable filing cabinets
- [ ] Locked room
- [x] Digital password protection
- [ ] Other

5.10. **Specify the precise location of the storage place(s).** (Room number, etc.)*

All data will be stored in Chief Investigators office ie Dr Markendeya Jois iffice, HS2- Room No- 447 and his computer, and in Marks absence for prolonged period Dr JencyThomas HS2-Room No- 429 and Dr Jessica Radcliff HS3- Room will be given access to the data who are also co-investigators in this project.

Following completion of the study:

5.11. **Indicate how the data, materials and records will be stored:***

- ○ All data will be entirely non-identifiable
- ◉ Data may be potentially identifiable (e.g. coded)
- ○ Data will be wholly identifiable

5.12. **Describe how the security of project documentation will be preserved and specify the precise location of the final storage place(s).***

All document will be stored securely in locked filing cabinets in Dr Jois's office and in the computer which only Dr Jois will have access with secure password and username.

5.13. **Indicate the minimum period for which data will be retained.**
Research data and records should be kept for as long as they are of continuing value to the researcher and as long as record keeping requirements exist (such as patent requirements, legislative and other regulatory requirements). The minimum retention period for research data and records is five years after publication/public release of the work (or 15 years for clinical trials). See help for definitions. *

- ○ Indefinitely
- ○ 5 years post publication
- ○ 7 years post publication
- ◉ 15 years post publication
- ○ 25 years after date of birth of participants
- ○ Other

5.14. **Will you transfer your data or materials to a managed archive or repository during the project, after the project, or after the retention period? If so, indicate which discipline specific or institutional archives will be considered.**
*Note that some funding agencies and publishers may require lodgement with an archive or repository. Contact ICT about the Research Data Store, or contact the Library for more information about the La Trobe University Research Repository (Research Online).**

Not Applicable

5.15. **If you specify to participants that you will destroy the data collected, what methods of appropriate disposal or destruction will be employed?**
When further retention of data and materials is no longer required, responsible disposal methods should be adopted. Disposal software should also be adopted if digital software, computer hardware, disks or storage media are reused or retired.

All data collected will be deleted permanently from the computer of the chief investigator. Blood samples collected will be destroyed via Biological waste disposal service at La Trobe Uni after the retention period is over.

Publication & Dissemination

5.16. **Indicate how the results of this research will be reported or published:***

- [x] Thesis
- [x] Journal article(s)
- [ ] Book
- [x] Research report to collaborating organisations
- [x] Conference presentation(s)
- [ ] Recorded performance
- [ ] Other

5.17. **Will participants be informed that results of the study may appear in the publication method(s) described above?** *

- ◉ Yes
- ○ No

5.17.a. If yes, provide details.
*Note that this information should be included in the Participant Information Statement and given to participants prior to obtaining informed consent.**

The participants will be informed via the Participant Information Statement that the data arising from this project will be potentially used towards publication in medical journals, conference presentations and PhD thesis.

5.18. **Will results from the study be available to participants on request?** *

- (•) Yes
- ( ) No

5.18.a. If yes, how will participants be notified that this is the case?
*Note that this information should be included in the Participant Information Statement and given to participants prior to obtaining informed consent.**

If the participants request for the results from the study, the investigators will send an email with an appointment time and they can come in on a specified time and date to collect the results. Results could be given via emails but during some occasions the participants would require interpretation of the results hence it is ideal for the participants to come in to collect the results.

5.19. **Will participants be informed that their personal data collected in the course of the research will be available to them on request?** *

- (•) Yes
- ( ) No

5.19.a. If yes, how will participants be notified that this is the case?
*Note that this information should be included in the Participant Information Statement and given to participants prior to obtaining informed consent.**

This information will be available to them on their first visit and will also be mentioned in the Participant Information Statement.

Section 6 - Finalise Application

Documents & Attachments

The following documentation must be attached to your application:

Copy of proposed Participant Information Statement(s) *(use the templates provided on the La Trobe University Human Research Ethics website)*

Copy of proposed Consent Form(s) *(use the templates provided on the La Trobe University Human Research Ethics website)*

Copy of proposed Withdrawal of Consent Form(s) *(use the templates provided on the La Trobe University Human Research Ethics website)*

Copy of proposed recruitment advertisements, flyers, advertising materials, etc.

Copy of proposed questionnaire(s)

Copy of funding application(s)

Copy of certification for all persons collecting samples of biospecimens

Copy of certification for all persons administering first aid

Evidence of approval from OHS or other relevant safety authority

Evidence of approval from Radiation Safety Committee

6.1. **Attach each of the items specifically listed above, as well as any other supporting documentation to the table below.***

Description	Reference	Soft copy	Hard copy
Participant Information Statement	Appendix 1-Participant Information Statement.pdf	✓	
Consent Form	Appendix 2-Consent Form.pdf	✓	
Evidence of approval from Radiation Safety Committee	Appendix 10-Radiation safety approval.pdf	✓	
First Aid Certificate	Appendix 14-First Aid Certificate.pdf	✓	
Participants' general information	Appendix 9-General Background of Participants.pdf	✓	
Questionnaire 1	Appendix 5-Sleep Quality Questionnaire.pdf	✓	
Questionnaire 2	Appendix 6-Depression Scale (CEDS-R) Questionnaire.pdf	✓	
Sleep Diary Form	Appendix 7-Sleep diary.pdf	✓	
Withdrawal of Consent Form	Appendix 3-Withdrawal of Consent Form.pdf	✓	
Declaration Form for External Investigators	No external Investigator		✓
Reference List	Appendix 13-Reference List.pdf	✓	
Advertising Material (flyers etc.)	Appendix 4-study flyer.pdf	✓	
Certification for sample collection	Appendix 11-DEXA and Venepuncture Certificates.pdf	✓	
Diet Diary Form	Appendix 8-Diet Diary.pdf	✓	
Ethically Defensible Plan on management of participants' information	Appendix 16-Ethically Defensible Plan describing the management of participants' information.pdf	✓	
Evidence of approval from OHS authority	Appendix 12-OHS approval, March 2016.pdf	✓	

Committee/Risk Assessment

If any statements appear below, this application must be reviewed by the University Human Ethics Committee.
These statements relate to projects considered to be Above Low Risk, or involve groups identified by the National Statement.

Question 2.16. Does the research involve the collection of human biospecimens (i.e. tissue or fluid samples, etc.) directly from participants?
You answered 'Yes'.

Question 2.19. Will the research discover or generate health information of potential importance to the future of participants, their blood relatives or their community?
You answered 'Yes'.

Question 2.20. Does the research involve the use of ionising radiation?
You answered 'Yes'.

If any statements appear below, this application may require review by the University Human Ethics Committee.
These statements relate to projects considered to be Above Low Risk in certain circumstances.

Question 2.9. Will the research potentially involve any participants in dependent or unequal relationships with any of the members of the research team or people involved in recruitment? For example, teacher/student, doctor/patient, student/lecturer, client/counsellor, employer/employee. Such relationships may compromise a participant's ability to give consent which is free from any form of pressure, real or implied.
You answered 'Yes'.

Question 4.1. Is there any risk of psychological, emotional, social harm to the participant or research team? This includes anything which may be experienced by participants as stressful, noxious, aversive or unpleasant during or after the research procedures.
You answered 'Yes'.

Question 4.5. Does the research involve any potential physical risks or harm to the participants and/or researchers?
You answered 'Yes'.

If any statements appear below, this application may be considered as Negligible Risk.
Such applications may not require formal review, please contact an Ethics Officer to discuss your application before submission.

If no statements have appeared above, this application should be submitted to the relevant College Human Ethics Sub-Committee to be reviewed as Low Risk.

6.2. **Considering the information above, which Committee do you wish to submit this application to?**
*Please note that the risk level will determine who reviews this application and will not necessarily influence the length of the review process. The Ethics Officer will assess your submission, then formally accept your application on behalf of the appropriate Committee.**

- (●) University Human Ethics Committee
- ( ) Arts, Social Sciences & Commerce College Human Ethics Sub-Committee
- ( ) Science, Health & Engineering College Human Ethics Sub-Committee

6.2.a. **Provide a short justification why you have chosen this committee to review your application based on the risks involved.***

This study involves all part of the community age between 18-65 and human bio-specimen will be collected in this study.

Declaration

Investigator Declaration

In preparing this application I/we, the undersigned, declare that I/we:

- have read and agree to abide by the La Trobe University Human Research Ethics Guidelines;
- have read and agree to abide by the conditions and constraints of the National Statement on Ethical Conduct in Human Research (2007) and any other relevant University and/or statutory requirements;
- accept responsibility for the accuracy of the information provided in this application and for the conduct of this research, in accordance with the principles contained in the NHMRC Guidelines and any other conditions specified by the University Human Ethics Committee;
- will ensure that the qualifications and / or experience of all personnel involved with the project are appropriate to the procedures performed;
- will ensure that appropriate permits from relevant external organisations, or State or Federal agencies will be obtained, that copies will be lodged with the UHEC and that any imposed conditions will be observed;
- understand that the information contained in this application is given on the basis that it remains confidential in accordance with relevant University and statutory requirements;
- abide by the terms and conditions set by the University Human Ethics Committee;
- certify that the information contained in this application is true and accurate;
- will seek approval for modifications to the research prior to their implementation.

6.3. **Declaration Table***

1	*Staff/Student ID*	00332318
	Full Name	Markandeya Jois
	Role in Research Project	Chief Investigator
	Personnel Type	Internal
	Sign Declaration? By clicking the checkbox below, you are agreeing to conduct the research project in accordance with the above declaration.	Yes
	Date Signed	24/03/2016
2	*Staff/Student ID*	00083115
	Full Name	Jency Thomas
	Role in Research Project	Associate Investigator
	Personnel Type	Internal
	Sign Declaration? By clicking the checkbox below, you are agreeing to conduct the research project in accordance with the above declaration.	Yes
	Date Signed	16/03/2016
3	*Staff/Student ID*	00059870
	Full Name	Jessica Radcliffe
	Role in Research Project	Associate Investigator
	Personnel Type	Internal
	Sign Declaration? By clicking the checkbox below, you are agreeing to conduct the research project in accordance with the above declaration.	Yes
	Date Signed	21/03/2016
4	*Staff/Student ID*	17530802
	Full Name	Surafel Tegegne
	Role in Research Project	Postgraduate Student
	Personnel Type	Student
	Sign Declaration? By clicking the checkbox below, you are agreeing to conduct the research project in accordance with the above declaration.	Yes
	Date Signed	21/03/2016

Submission Details

Reminders

- All applications must be sighted and approved by all members of the research team and any relevant parties. Please ensure each member of the research team has completed their declaration in "Section 6 - Declaration" above, including any declaration forms supplied on behalf of External Investigators. *Applications will not be reviewed without appropriate authorisation.*
- It is strongly recommended that you save a PDF version of your application before submitting as you will lose access to the electronic record while it undergoes formal review.
- All investigators will receive a confirmation email once this application has been successfully submitted.
- You can check on the progress of this application at any time by viewing the "Process Status" information on the My Applications page.
- *Note: Only a Chief Investigator is able to submit an application for ethical approval. The Chief Investigator who is marked as the primary contact for this application is:*

Markandeya Jois

You are reminded that your project may not commence without formal written approval from the University Human Ethics Committee (UHEC) or College Human Ethics Sub-Committee (CHESC).