PARTICIPANT INFORMATION LETTER

PROJECT TITLE: Nocturnal blood glucose responses to potato-based mixed evening meals

PRINCIPAL INVESTIGATORS: ***Dr Brooke Devlin & Professor John Hawley***
CO-INVESTIGATORS: ***Dr Evelyn Parr & Miss Bridget Radford***

Dear Participant,

You are invited to participate in a research project conducted by the Centre for Exercise and Nutrition, Australian Catholic University (ACU) described within this Participant Information Letter. This document informs you about the research project; it explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you choose to take part. If you decide you want to take part in the research project, you will be asked to sign the consent form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described

What is the project about?

Potatoes are relatively nutrient dense yet are often avoided as they are perceived as a high glycaemic index (GI) food and are negatively associated with carbohydrates. Whilst the GI of potatoes has been well documented, these values vary and do not accurately represent their effect on blood glucose when consumed as part of a mixed meal as they normally would be in a real world setting. The cooking method may also alter the glycaemic response. In healthy populations, low GI diets are promoted as beneficial for weight loss and spikes of high blood glucose have been associated with increased risk of cardiovascular disease. People with type 2 diabetes (T2DM) are frequently encouraged to avoid high GI foods to reduce average blood glucose levels and prevent diabetes related complications. Therefore, the aim of this study is to evaluate glucose response following consumption of a potato-based mixed meal in both healthy individuals and persons with type 2 diabetes.

Who is undertaking the project?

This project is being conducted under the supervision of Professor John Hawley in the Centre for Exercise and Nutrition within the Mary MacKillop Institute for Health Research at the Australian Catholic University (Melbourne). The co-ordinator for this study will be Dr Brooke Devlin. Dr Brooke Devlin is a Research Fellow at ACU, an Accredited Practising Dietitian (APD), a qualified DXA technician and the research dietitian within the Centre for Exercise and Nutrition. Dr Evelyn Parr, a Research Fellow at ACU who has experience with previous research projects involving all of the measures being taken in the current study, is a co-investigator. Dr Parr is experienced in venepuncture (with certification), regular blood drawing for oral glucose tolerance tests and is a qualified DXA technician. Miss Bridget Radford is also a co-investigator who has been involved in several diet-monitored studies at ACU. All researchers that are involved have first aid training.

The project has been approved by the ACU Human Research Ethics Committee (2017-263H) and is supported by a grant from the Alliance for Potato Research & Education (APRE) to Dr Brooke Devlin and Professor John Hawley. APRE will not have any influence over the conduct of the study, dissemination of results or access to confidential data.

What does participation in this research involve?

Participation in this project will involve **a minimum of 18** separate visits to the Centre for Exercise and Nutrition at the Australian Catholic University. The study protocol (below) summarises the study procedures. The visits you will be required to attend the lab (located in Room 1.03 in the Daniel Mannix Building, entrance via 17 Young Street or 8 - 18 Brunswick Street, Fitzroy) are outlined on the following pages.

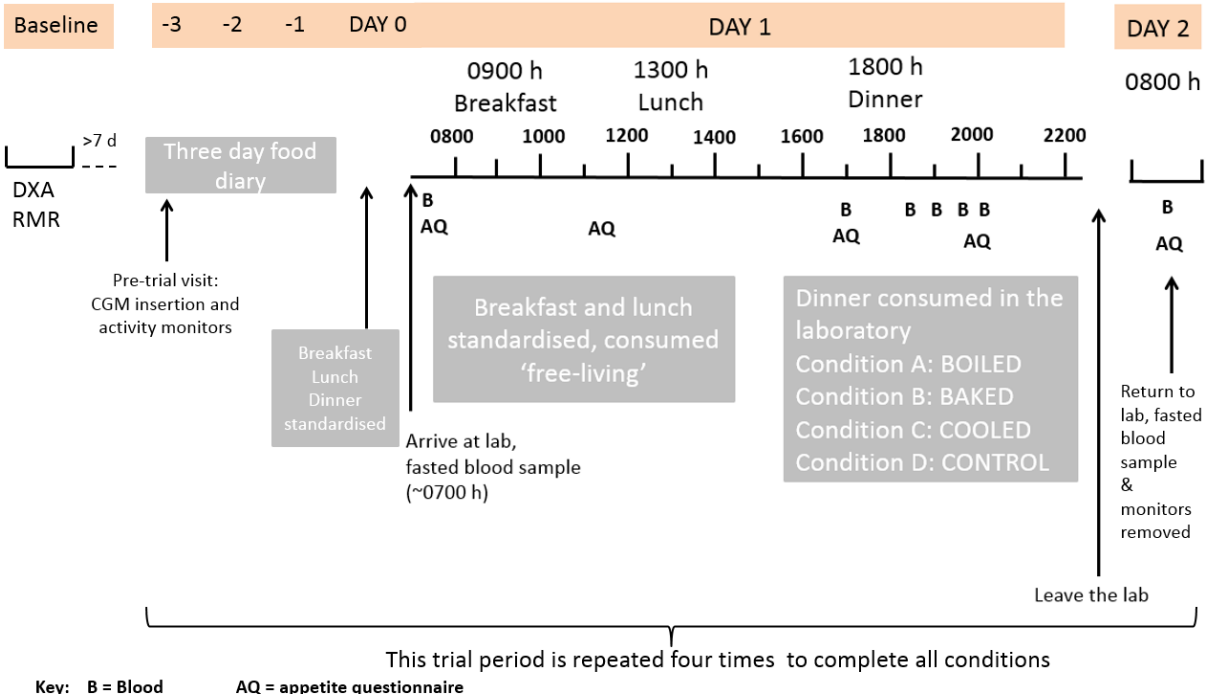

Figure 1. Timeline and description of procedures.

Visit 1: Pre-study visit (∽ 30 minutes)

Initial screening will take place via telephone followed by a pre-study visit at the lab. Screening will assess relevant medical history, age and self-reported height/weight (in order to calculate BMI). Forty volunteers will be recruited to participate in this study according to the following inclusion criteria:

- Either diagnosed with T2DM or normal glucose tolerance
- Aged between 35 and 65 years
- BMI between 22 and 35 kg/m^2

During your pre-study visit, you will meet with the study investigators who will thoroughly explain the study procedures, measure your height and weight, show you the facilities where the trials will take place and give you the opportunity to ask any questions and clarify any concerns. If you decide to participate in this study and meet the selection criteria, a consent form will need to be signed prior to any assessments being performed. You will also be asked to read and sign other relevant documents. You will be given a hard copy of this Participant Information Letter and the consent form.

Visit 2: Baseline measurements (∽ 1.5 hours)

A baseline measurements visit will be arranged to measure body composition, resting metabolic rate and blood pressure. Anthropometric measurements will also be obtained and researchers will explain how to record your dietary intake.

- **Anthropometric measurements (∽ 5 minutes):** Height will be measured using a wall mounted stadiometer. Weight will be measured using digital scales. Hip, waist and neck circumference will be measured with a metal tape measure. All measures will be taken in duplicate.
- **Body composition assessment (∽ 30 minutes):** A dual-energy x-ray absorptiometry scan (DXA) is a specialised x-ray technique to provide a measure of body composition. This is similar to a normal x-ray, with no pain involved and will obtain a measure of total body mass, fat mass and lean mass. Participants are required to lay supine on the scanning bed for the duration of the scan, which is approximately 15 minutes and will be one to two scans depending on your body shape. The machine uses **small doses (< 1% of the yearly radiation dose) of radiation** to estimate tissue density. This test **requires you to be fasted** with no food, fluid or exercise/activity prior to the test and requires you to wear light clothing with no metal items (i.e. zips, domes, clips, underwire etc.) and remove all jewellery. Please check with the research staff if you are unsure. All measures will be taken by trained researchers, Dr Evelyn Parr and Dr Brooke Devlin.
- **Resting Metabolic Rate (∽ 25 minutes):** This assessment also involves you being fasted and therefore will be completed immediately after the DXA san. For 25 minutes you will be lying in a quiet, dim-lit room where we can measure your resting metabolic rate using an automated gas analyser. A hood, as in the picture below, will go over your head and is connected to the gas analyser. There is a 10 minute rest period followed by a 15 minute period where the data will be collected. The information from this test will also be used to give an assessment of estimated energy requirements for comparison with your dietary intake information.

- **Blood pressure measurement (∽ 5 minutes):** Blood pressure will be measured via an automated blood pressure machine. Three measures will be taken. Each measure is approximately 3 minutes in duration. A cuff will be applied to the upper portion of the arm. This will inflate and tighten around the arm and then slowly release.
- **Three day food record explained (∽ 5 minutes):** You will be asked to record ALL food and fluid consumed over the three day periods prior to each condition to establish habitual dietary intake and standardise diet prior to all trials. To assist with compliance, and reduce the burden on you, household measures will be recorded. A comprehensive document will be provided and this will be explained to you in detail at this visit by the study dietitian. Prior to each condition, you will be asked to replicate, as closely as possible, the dietary intake consumed in the lead up to the first experimental condition whilst still recording dietary intake during this time.

Visits 3, 6, 9 & 12 (Day - 3): Monitors and provision of standardised meals (∽ 1 hour)

A continuous glucose monitor (CGM) and three activity monitors will be inserted/put on to monitor blood glucose and physical activity in the four day period prior to all four trials, each trial day and the following morning.

- **Continuous glucose monitor (CGM) (∽ 10 minutes):** The minimally invasive Medtronic iPro2 blood glucose monitoring system records blood glucose level every 5 minutes whilst you are able to conduct normal daily activities. To calibrate the sensor, with each period of wearing the CGM, you will be provided with a hand-held blood glucose monitor to measure and required to take finger prick blood glucose samples four times a day. The CGM is the size of a 50 cent piece and the associated sensor inserted rather painlessly into the subcutaneous tissue of the lower back. Following the insertion, you will remain in the laboratory for an hour to able calibrate the machine with the first finger prick and also to learn how to use the hand-held glucose monitor.
- **Activity monitors (∽ 10 minutes):** To assess physical activity and sleep patterns, you will be fitted with an ActivPal, ActiGraph and SenseWear. Additionally, you will be asked to complete an activity and sleep record. These monitors will need to be worn and the record completed for each four day period prior to each trial.

  The **ActivPal inclinometer** records information regarding the frequency and duration of times spent sitting, standing and walking. This will be fixed to the front of your upper thigh with a micropore dressing to be worn through waking, sleeping and showering/bathing. The research staff will provide you with replacement micropore tape if you need to switch legs because of irritation with the dressing. If this occurs, please consult one of the research team.

  The **ActiGraph accelerometer** records information regarding the speed of movement patterns and is worn over the right hip using a belt around the waist. The ActiGraph will only be worn during waking hours (i.e. not overnight).

  The **SenseWear armband** records sleep patterns. This will be worn around the tricep muscle (upper arm) for waking and sleeping hours, removing it for showering/bathing.
- **Standardised meals provided (∽ 10 minutes):** To ensure your dietary intake is the same in the lead up to all trials, you will be provided with a standardised breakfast, lunch and dinner to consume in the 24 h period prior to each trial day. You will also consume these meals on the trial day (dinner meal will differ between condition and between Day 0 and Day 1). Researchers will

explain what food is to be consumed and when and this information will be outlined in a comprehensive handbook. The amount of food provided will be based on calculations using results from your RMR test and DXA scan. This will help ensure we are proving you with neither excess or too little portions. Food items can be substituted where there is an intolerance, allergy or dietary constraints that do not permit the set food items (e.g. vegetarianism). Breakfast will consist of cereal, milk and toast. Lunch will be a ham and cheese sandwich with yoghurt and dried fruit. The dinner meal will consist of meat, vegetables and either RICE (Day 0) or POTATO/WHITE BREAD (Day 1) as per Condition A-D**.**

Visits 4, 7, 10 & 13 (Day 1): Trial day

- **Visit 4 - AM: Blood sample and meal collection (∽ 30 minutes):** You will arrive at the lab at *0700 h* after an overnight fast. A fasted blood sample (18 mL) will be obtained from forearm vein for subsequent analysis of glucose, insulin, free fatty acids and appetite hormones. You complete an appetite/satiety questionnaire prior to consuming breakfast at the lab. Researchers will provide you with lunch to be consumed in your "free living" environment that day.
- **Visit 4 - PM: Blood sampling and potato meal/control consumption (∽ 3.5 hours):** At *1700 h* you will return the lab to complete one of the four conditions (in a random order) outlined as follows:

  Condition A - Dinner of BOILED potato, meat (protein) and vegetables;
  Condition B - Dinner of BAKED potato, meat (protein) and vegetables;
  Condition C - Dinner of BOILED THEN COOLED potato, meat (protein) and vegetables;
  Condition D - Control dinner of white bread, meat (protein) and vegetables.

  A cannula will be inserted into a vein in your arm and will remain there for the duration of the study visit. Blood samples will be collected upon arrival and then at 30, 60, 90 and 120 min after the dinner meal is consumed at *1800 h*. Each time a blood sample is taken, a small volume of sterile saline will be injected to keep the cannula clear and unblocked for subsequent sampling. You will complete an appetite/satiety questionnaire twice during this visit.

Visits 5, 8, 11 & 14 (Day 2): Blood sample and monitor removal (∽ 30 minutes)

On the day following the trial day, at *0700 h,* you will return to the lab where a final fasted blood sample will be obtained and your activity monitors and CGM will be removed. No more than 140 mL will be collected over each trial period.

Following a minimum 7 day "washout period", where you return to your normal habitual diet, between each trial **you will re-attend the lab and repeat visits 3 – 5 until all four conditions are completed.** Visits 3 – 5 will occur a total of FOUR times with a minimum of seven days between trials in order to complete all conditions.

Are there any risks associated with participating in this project?

As a participant, you will be exposed to some risks arising from the study. Appropriate measures will be taken to provide you with the safest possible testing environment. The invasive procedure (blood sampling) will be conducted by a certified phlebotomist under sterile conditions and using single use sterile equipment. The risks associated with participation in this study are:

Blood sampling – 18 mL blood samples will be obtained throughout the trial. Seven samples will be collected during each of the four trial periods (28 samples in total). The total volume collected (504 mL)

across the minimum 6 week period, is minimal compared to the standard 500 mL for a Red Cross donation collected in one sitting. Blood sampling may cause some discomfort or possible bruising. Sometimes, the blood vessel may swell, or a clot may develop in the blood vessel or there can be a minor bleeding. Although the possibility of significant bruising or bleeding is small, if by chance it does eventuate, consult your doctor immediately and inform the study coordinators (Dr Brooke Devlin or Dr Evelyn Parr).

Dual-energy x-ray absorptiometry – This procedure provides an estimate of your body composition (fat and lean mass). The scan takes ~15 minutes and will be one to two scans depending on your body shape. The machine uses **small does (<1% of the yearly radiation dose) of radiation**.

Continuous Blood Glucose Monitoring – This will involve having a tiny sensor inserted into the skin of your lower back. Insertion is quick and virtually painless. The sensor sits just beneath the skin, is comfortable to wear and generally becomes unnoticeable over time. The sensor is connected to a data monitor (size of a 50 cent piece), which continuously records the blood glucose readings. Irritation or inflammation may occur at the sensor site, but this is unlikely as the device is minimally invasive. If you do have any issues then please contact the study coordinator immediately.

Activity monitors - Some participants may experience a minor skin irritation with having the micropore tape over the ActivPal. If this occurs, participants can remove the ActivPal and adhere it to the other leg for the remaining period. Participants will be supplied with spare micropore, as well as two clear, plastic dressings for this purpose.

Participation in this study can be suspended or terminated if a medical issue or distress occurs. There may be additional unforeseen or unknown risks.

What are the benefits of the research project?

We cannot guarantee or promise that you will receive any benefits from this research. However, potential personal benefits may include an understanding of your current blood profiles, glucose response, activity patterns and measurements of body composition and resting metabolic rate.

Can I withdraw from the study?

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time without adverse consequences. However, if you decide to leave the project, the researchers would like to keep the personal and health information about you and any blood samples that have been collected. This is to help them make sure that the results of the research can be reported properly. If you do not want them to do this, please advise them before you join the research project.

Will anyone else know the results of the project?

All information that you provide as part of your participation in the study will remain confidential and private. No publications arising from the study will contain names or other identifying information. Randomly assigned codes will be generated to identify all data such that no personal details will be linked to any measures you provide for this study. Samples will be destroyed in line with the ACU privacy policy following publication or 5 years post investigation.

Only at your request, will study personnel disclose medical results to your primary care physician or specialist. Data records will be kept securely in a non-identifiable format and will only be accessible by research staff. These records will be retained by the University for five years following publication, or five

years following the completion of the project. After this period, data will be disposed of in accordance with the ACU's privacy policy.

Will I be able to find out the results of the project?

Once the study has been completed you will be provided with a summary of both your individual results and group data by mail. If the study results are published in a scientific journal you will also be sent a copy of the publication. You are free to ask questions of our research staff at any time during the study.

Who do I contact if I have questions about the project?

Bridget Radford, can be contacted at any time on (03) 9230 8284 or via email bridget.radford@acu.edu.au. Alternatively, you can contact either of the principal researchers - Dr Brooke Devlin on 0401 825 095/ brooke.devlin@acu.edu.au or Professor John Hawley, on (03) 9953 3552.

Reimbursement for costs

There are no costs associated with participating in this research project, nor will you be paid. However, you will be reimbursed $300.00 for participating in the research project to cover any costs incurred with the appointment schedules and travel/parking.

What if I have a complaint or any concerns?

If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research). Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

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I want to participate! How do I sign up?

If you would like to participate in this research study, please contact Bridget Radford on (03) 9230 8284 or bridget.radford@acu.edu.au to determine if you are a suitable candidate and have a pre-screening phone call.

Yours sincerely,

Dr Brooke Devlin & Professor John Hawley
Principal Investigators

Dr Evelyn Parr & Miss Bridget Radford
Co-investigators