# PLAIN LANGUAGE STATEMENT AND CONSENT FORM

**TO:****Participant**

**Plain Language Statement**

**Date:** …**…………………………..**

**Project Title:** Effect of pre-sleep α-lactalbumin supplementation in a trained population with sleep difficulties

**Principal Researcher:** Dr Dominique Condo

**Student Researcher:** Mr Jackson Barnard

**Associate Researcher(s):** Professor Brad Aisbett, Dr Michele Lastella, Dr Spencer Roberts

The Plain Language Statement and Consent Form contains 14 pages. Please make sure you have all the pages.

## 1. Your Consent

You are invited to take part in this research project.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project so that you can make an informed decision whether you are going to participate.

Please read all sections of this Plain Language Statement carefully. Please feel free to ask questions about any information contained within this document. You may also wish to discuss the project with a relative or friend or your local health worker.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Plain Language Statement and Consent Form to keep as a record.

## 2. Purpose and Background

Researchers are investigating the effect of α-lactalbumin intake (protein high in tryptophan) on sleep, cognitive and mood outcomes within trained individuals experiencing sleep difficulty. Sleep improves the health, well-being and performance of individuals undergoing training, so this study aims to investigate a practical nutritional aid in attempt to improve sleep quality. The impact of diet on sleep is a growing area of research interest, with reports that protein intakes high in tryptophan may benefit sleep, especially for those experiencing sleep complaints. In addition to sleep, the intake of α-lactalbumin may improve mood and cognitive performance of an individual. The proposed mechanism by which sleep, mood and cognition are affected is through increases in tryptophan availability to the brain, which can be measured through blood plasma concentrations. The effect of α-lactalbumin intake on these measures has not been completed within a trained population with sleep difficulties.

## 3. Eligibility

Firstly, to determine if you are eligible to participate in the study, you will be asked to fill out some simple questionnaires to determine current sleep quality. These questionnaires include the 16-question Athlete Sleep Screening Questionnaire (ASSQ), and the Pittsburgh Sleep Quality Index (PSQI). If you take >15 minutes to fall asleep, and are calculated to have a sleep difficulty score ≥5 as per the ASSQ, and global score >5 as per the PSQI, you will be eligible. If any of these factors relate to you, you may be excluded from the study: smoking, excessive alcohol consumption (>17 standard drinks per week), dairy allergy, high caffeine use (e.g., >5 mg∙kg-1∙d-1), antidepressant or sleep medication use, current or recently finished night shift work, recent transmeridian travel, fluctuating bedtimes, and pregnancy.

***Relevant only to female participants***

Females will be required to be naturally menstruating or taking an oral contraceptive pill. A menstrual cycle questionnaire is to be filled out at the screening phase to determine eligibility. Naturally menstruating females will be to participate in the intervention sessions during the early follicular phase (coincides with menses), as this is when the influence of female hormones is low, which can otherwise impact sleep. If you are taking an oral contraceptive pill, depending on the type, participation in the study will take place between days 3-21, or 12-21 of the 28-day pill cycle.

Menstrual phase will be determined by tracking of your menstrual cycle for two consecutive cycles prior to the study, during the study and for one cycle post-study.

## 4. Procedures

We would like to invite you to participate in a research study in which we will examine the effect of α-lactalbumin on your sleep, recovery, cognition, mood and amino acids within the blood. A graphic overview is provided below in Figure 1.

Please note, before attending the Deakin Burwood campus, a COVID-19 questionnaire is to be completed.

### Screening

Firstly, we will require you to complete a baseline screening session, where you are to complete the ASSQ and PSQI to determine sleep quality and difficulty, and the Morningness-Eveningness Questionnaire to determine chronotype (e.g., early bird or night owl). Training status will also be assessed by training diaries, where you will list the amount of light, moderate, vigorous/high (intensity) training sessions completed per week (frequency) and session durations. If you meet the inclusion criteria, you will be asked to present for a familiarisation session.

### Familiarisation Session

One-week prior to the study, you will come into Deakin University to practice simple cognition tasks on a tablet, which should take ~7 minutes. These tasks will test your attention, spatial awareness, reaction time, and visual tracking. You will also be required to stay overnight to become familiar with the sleeping environment and sleep equipment (DREEM headband). You are to wear the headband from when you initiate sleep until you awake (which shouldn’t cause discomfort). Simple height and weight measures are to be taken at this time also. As you will be able to continue your normal training sessions throughout the study, you will be given a tour of the facilities you will have access to complete these sessions (e.g., sports science gym).

### Baseline Measures

Following familiarisation, your sleep, diet, and training is to be monitored for a five-day period (including one weekend day). A five-day food record is to be completed using a smartphone app (Easy Diet Diary), to quantify your normal dietary intake, as well as to establish any dietary allergies and/or sensitivities. This informs the researchers how to best cater to your energy needs for dietary standardisation, with meals to be provided to you during the intervention periods.

Sleep will be monitored for five days via an activity monitor (actigraph) and sleep diaries. The activity monitor is a small watch-like device typically worn on the non-dominant wrist to record sleep and physical activity levels. Your average bedtime and wakeup times across this five-day period will become your ‘prescribed’ sleep/wake times over the course of the study. This means that for the duration of the study, you are to go to sleep and rise at set times for both intervention periods and the wash-out, which will be described further below. Within the sleep diary, there are items related to bedtime, wake time, and sleep quality (1-5 scale). Please note, the activity monitor is to be used as a control for sleep and physical activity output throughout the entire trial, and therefore is required to be worn for the entirety of the study (except when swimming or showering).

Training will be monitored through a five-day training diary, which enables researchers to quantify your typical training loads and sessions, which will detail the sessions that you will complete throughout the intervention periods. The non-invasive activity monitor to be worn for the whole study will also measure your physical activity output. You will be randomly allocated into the experimental or placebo group, in a crossover design (you will complete both conditions). Both you and the research team will not be aware which group you are assigned to so that the trials are not biased. The experimental group will receive 40 g α-lactalbumin (BiPRO Alpha 9000; Agropur Inc, Appleton, WI), while the placebo will receive 40 g collagen protein (Collagen Regenerate; Body Science, Burleigh, QLD) drink. For the study, we will require you to stay overnight at the Deakin University laboratory on seven occasions, which includes one familiarisation session.

### ***Day 1 (intervention)***

You will be required to report to the university at **17:00**. Within the first hour of arrival, a trained researcher will insert a cannula into a forearm vein for later blood samples to be taken. You will be provided a low-protein dinner, at least 4 hours prior to prescribed bedtime. Next, 2-hours before bedtime, blood will be drawn immediately before you consume either the experimental or placebo protein drink (should be drank within 10 minutes). Small amounts of blood will be drawn (5 mL) at half an hour increments from supplement ingestion, until bedtime (pre supplement, 30-, 60-, 90-, 120-minutes post supplement). A simple questionnaire to assess sleepiness will also be completed at these same time points. Also, 30-min prior to bedtime, a short mood and recovery questionnaire is to be completed. At bedtime, the DREEM headband is to be worn, which will measure sleep metrics such as duration, quality and brain wave activity.

### ***Day 2 (intervention)***

A sleep diary (also containing the same mood, recovery and sleepiness questionnaires) is to be filled out 30 min after waking. Forty-five minutes after waking, four cognitive tests (app-based) will be completed to assess vigilance, spatial orientation, visual tracking, and reaction time. During the day, no formal testing is to be completed, but you may complete a typical training session (or no training as per your schedule provided in the baseline measures). To limit differences between intervention periods that may affect sleep, you should replicate your training schedule for both intervention periods. After the session, there is a brief training log to fill out which details exercise duration, type, and rating of perceived exertion (1-10 scale).

During the evening, the same supplement and testing protocols will be followed, however, blood sampling is only completed on the first night of each intervention period.

### ***Day 3 (intervention)***

This will be the same as day 2.

### ***Day 4 (intervention)***

After completing the sleep diary and cognitive testing in the morning you will enter the wash-out period, where you will return home for a minimum five days (females may require longer wash-out periods to limit hormonal influence on sleep). On day 4, you will also be required to complete a training log, if completing a training session.

### Wash-out (minimum five nights)

The wash-out phase is designed to limit any carry-over effect of the supplements going into the next intervention period, ensuring that the interventions are adequately separated. During the wash-out period, you will be required to continue wearing an activity monitor (actigraph), continue observing the ‘prescribed’ bedtime and completing the sleep diary. This is a control to ensure your sleeping pattern stays consistent so that sleep outcomes are not affected for the second intervention period. During this wash-out period, no supplement will be provided, and you may eat as per usual. Those observing an extended wash-out period (i.e., females), will only be required to wear the activity monitor, adhere to the set sleep/wake times, and complete the sleep diaries five days leading into the next intervention period.

### Days 1-4 (second intervention period)

The methods will be replicated exactly for the second intervention period. The only difference is that you will switch experimental groups and receive the opposing supplement (e.g., first intervention period = 40 g collagen, second intervention period = 40 g α-lactalbumin)

### Living Conditions:

Throughout the intervention periods, you will stay overnight within Deakin University Nursing laboratories at the Burwood campus. You will have your own bed (encouraged to bring pillows or anything from home that will increase comfort), as well as a common room with kitchen and TV facilities to share with other participants (maximum four participants completing the study at a time). Further, you will have access to the sports science (Building U) gym to complete your training session throughout the day. Standardised dietary meals will be provided (3x main meals + 2x snacks) throughout the intervention periods to provide you with 1.2 g/kg/day daily protein, and energy matched to your habitual intake (as determined through your 5-day food record). Except for water and approved low-protein snacks, external food or beverages outside of the provided meals will be prohibited, as this may decrease the effectiveness of the supplement. Also, throughout the intervention periods, caffeine consumption after 12 pm will be prohibited, along with evening use of electronic devices (e.g., phone, iPad).

Please note, you are to observe current COVID-19 health advice at the time of testing.

During the wash-out period, you will not be required to attend the University laboratory and are to eat as per your normal diet.

### Study Measures:

* Height (cm), weight (kg), sleep difficulty score, chronotype
* Sleep outcomes via DREEM headband (total sleep time, sleep latency, sleep efficiency, wake after sleep onset, fragmentation, and sleep architecture) – activity monitor to objectively measure sleep for the entire study as a control (including wash-out period)
* Subjective sleep (e.g., bedtime, sleep quality) through completion of sleep diary each morning
* Mood, recovery and sleepiness in the morning and evening via simple questionnaires
* Plasma tryptophan, large neutral amino acids and melatonin. These will be assessed within blood samples collected on the first night of each intervention period
* Cognitive performance assessed via smart device
* Training output as measured through training diaries and activity monitor

### Participant Commitment:

* 1 night at Deakin University Burwood campus for familiarisation session (1-week before study commencement)
* 3 nights at Deakin University Burwood campus for each intervention period (6 nights total – separated by a minimum 5-night wash-out period)
* During the intervention period, you may complete a training session within the sports science gym (Building U)
* A cannula will be inserted on the first night of each intervention period (2 occasions total), with five blood samples to be taken on these days.

Time commitment each day of the intervention periods:

- total time taken to complete cognitive testing, questionnaires, and diaries is estimated at ~30-45 minutes.

Figure 1. Graphic overview of the study.

## 5. Collection of Blood Samples

By consenting to take part in this study, you also consent to the collection and use of blood samples as specified below. Blood samples will be taken via cannulation of a vein in your forearm at five timepoints on day one of each intervention period. These blood samples will be stored in the laboratory freezer for later analysis of amino acids and melatonin within blood plasma.

## 6. Possible Benefits

Previously, α-lactalbumin has improved sleep parameters such as sleep latency and wake after sleep onset, as well as depressive symptoms and reaction time within populations with sleep complaints. Within a trained population, evening supplementation of 40 g α-lactalbumin resulted in increased N-REM stage 2 sleep, which have moderated to some extent, improved intermittent sprint performance the next day. However, more investigational trials such as this need to be conducted to conclude that α-lactalbumin does improve these measures. Due to the investigative nature of the α-lactalbumin, it is yet to be approved by the TGA. The α-lactalbumin provided is commercially available in the USA and is approved by the Food and Drug Administration for use as a food ingredient. Additionally, as this is the first study investigating the effect of α-lactalbumin within a trained population with sleep difficulties, results cannot be guaranteed and are hypothetical in nature.

The α-lactalbumin may be able to assist you in falling asleep and achieving better quality sleep throughout the night. Through improving your sleep, your cognition, recovery, mood, and daytime sleepiness may also be improved. By participating in this research, you will help to determine the effectiveness of α-lactalbumin in an athletic population, thus guiding future sports nutrition recommendations and guidelines.

## 7. Possible Risks

There are few foreseeable risks throughout this study albeit minimal, including risks associated with blood sampling, exercise, and food intolerance/allergies. There is a risk of bruising at the blood collection site, along with a small risk of infection. Researchers carrying out the blood sampling will be certified for this procedure, thereby reducing the risk of bruising. Infection risk is minimised by the use of sterile equipment for blood collection. The amount of blood taken throughout this study is minimal (5 mL samples). Exercise sessions completed within the sports science gym will be supervised to ensure your safety. Any food sensitivities or allergies should be disclosed, as food will be provided throughout the intervention periods. Any lactose intolerance or dairy allergies will exclude you from participating in this study, as both the α-lactalbumin and casein (placebo) are dairy-based proteins. In case of emergency (e.g., allergic reaction), researchers will become unblinded to your experimental group to know which supplement/food item was consumed.

Alpha-lactalbumin is not approved by the Therapeutic Goods Administration, however, has been supplemented previously in multiple studies at a 40 g dosage. The α-lactalbumin supplement used in this study has received Generally Regarded as Safe (GRAS) approval by the US Food and Drug Administration.

In addition to the risks outlined in this document, we recognise the challenging circumstances the COVID-19 pandemic has caused for many community members. As such, we would like to highlight that if you, or those close to you are experiencing distress, or are in need of additional support, you are encouraged to contact Beyond Blue on 1300 22 4636 or beyondblue.org.au.

## 8. Privacy, Confidentiality and Disclosure of Information

Any information obtained in this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law. Forms with identifying information will be stored using secure password protected software, with any physical copy of data stored within a locked filing cabinet when not in use.

A unique participant ID code will be used on all forms and data collected from you, and not with your name or any other identifying information. These data will be stored on a password protected Deakin network. Only the investigators at Deakin University will have access to this data. Any sharing of data with investigators outside of Deakin will occur only in a coded, anonymous way, with no identifiable or personal information to be shared.

The results of this study will be presented at scientific conferences, in scientific journals and research theses, with all information provided to remain anonymous. Your identity and personal information will not be disclosed. As a clinical trial, data is required to be retained for a minimum of 15 years as per research conduct policy.

## 9. Results of the Project

Upon completion of all testing sessions, there is an option on the consent form to be provided with information about your personal results (i.e., sleep outcomes, mood, cognitive performance). You will be provided with the final research report once it has been published. A member of the research team will send this information to you via email. Please indicate on the Consent Form attached below if you would like to receive this information.

Any results, which may require further clinical investigation will be documented, and with consent, a letter will be provided to you to be given to your general practitioner. The research staff will not use the results to diagnose any medical conditions.

## 10. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part in this project, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the research team, the School of Exercise and Nutrition Sciences, or Deakin University. You will also have the option to withdraw any data collected from the study should you wish to do so.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team and sign the withdrawal of consent form before withdrawal. Please also indicate whether you wish to withdraw any previously collected information from the study.

## 11. Payments to Participants

You will not be paid for your participation in the trial

## 12. Further Information

If you require any further information or if you have any problems concerning this project you can contact the Principal Researcher Dr Dominique Condo, or the Student Researcher - Mr Jackson Barnard.

Dr Condo will be available at:

Work email: dominique.condo@deakin.edu.au

Work telephone: 03 9251 7309

Mr Barnard will be available at:

Work email: jgbarnard@deakin.edu.au

Mobile telephone: 0430756550

## 13. Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number (2021-XXX).

## 14. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (June 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

As per good clinical practice, this research will undergo continuous monitoring in the form of annual reports. Given the small sample size and capacity of participants undergoing the study at one time, Dr Condo (CI) will monitor participants throughout the study to ensure there are no adverse effects of taking the supplement. This is unlikely given it is a food product safe for human consumption. This will occur daily across the three-day intervention and once in the washout period.

## 15. Source of Funding

This research is funded by seed funding from the Centre for Sport Research at Deakin University.



# PLAIN LANGUAGE STATEMENT AND CONSENT FORM

**Consent Form**

**Date:** …**…………………………..**

**Project Title:** Effect of pre-sleep α-lactalbumin supplementation in a trained population with sleep difficulties

**Reference Number:** (2021-XXX)

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I have read and I understand the attached Plain Language Statement

I freely agree to participate in this project according to the conditions in the Plain Language Statement

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The aims, methods, anticipated benefits, and possible risks of the research study have been explained to me.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public forum.

I understand that I am free to withdraw my consent at any time during the study, in which event my participation in the research study will immediately cease.

I extend my consent for the use of my data in future research projects that are extensions of, or closely related to, the original project or in the same general area of research 🞎

Do you wish to receive a final publication of this study? **(Yes / No)**

Do you wish to receive individual data regarding your results?  **(Yes / No)**

If you answered ‘Yes’ to either of these questions, please provide your email address below:

…………………………………………………………………………………………………………………………………..

Participant’s Name (printed) …………………………………………………………………………..

Signature: …………………………………………………………….. Date: ……………………………..



# PLAIN LANGUAGE STATEMENT AND CONSENT FORM

**Withdrawal of Consent Form**

*(To be used for participants who wish to withdraw from the project)*

**Date:** …**…………………………..**

**Project Title:** Effect of pre-sleep α-lactalbumin supplementation in a trained population with sleep difficulties

**Reference Number:** (2021-XXX)

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I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University*.*

I also wish to WITHDRAW any previously collected data from the study 🞎

Participant’s Name (printed) …………………………………………………………………………..

Signature: …………………………………………………………….. Date: ……………………………..

**Please return this form in person, mail or email to:**

**Jackson Barnard**

School of Exercise and Nutrition Sciences

221 Burwood Highway Burwood 3125, Victoria

0430756550

jgbarnard@deakin.edu.au