# PLAIN LANGUAGE STATEMENT AND CONSENT FORM

**TO:****Participant**

**Plain Language Statement**

**Date:** …**…………………………..**

**Project Title:** Effect of pre-sleep α-lactalbumin supplementation on the sleep and performance of athletes with sleep difficulties within habitual environments

**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, mood, and performance outcomes within athletes experiencing sleep difficulty. Sleep is essential for optimal health and wellbeing, with inadequate sleep being a risk factor for illness, injury, and poor performance within athletes. As many athletes’ experience sleep difficulties, this study aims to investigate a novel, practical nutrition aid to improve sleep. The impact of diet on athlete sleep is an area for further investigation, with protein quantity, composition, and timing seen to influence sleep differently. For example, consumption of high tryptophan protein sources in the evening is associated with a reduced time to fall asleep. This sleep-inducing effect of evening protein intake is believed to be increased in people that struggle to fall asleep. Athletes that have difficulties with their sleep are prone to accumulating sleep debt, which may exacerbate declines in sporting performance, especially endurance-based performance. With the effectiveness of α-lactalbumin having not been assessed over a duration longer than 3 days, this study will help determine the impacts that sub-chronic supplementation has on athlete performance, mood, and sleep.

## 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. Additionally, you are to be actively competing in a team-sport and registered with a club at a minimum community level. Further, if any of these factors relate to you, you may be excluded from the study: smoking, excessive alcohol consumption (>17 standard drinks per week), <18 years of age, 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 commence the intervention periods 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.

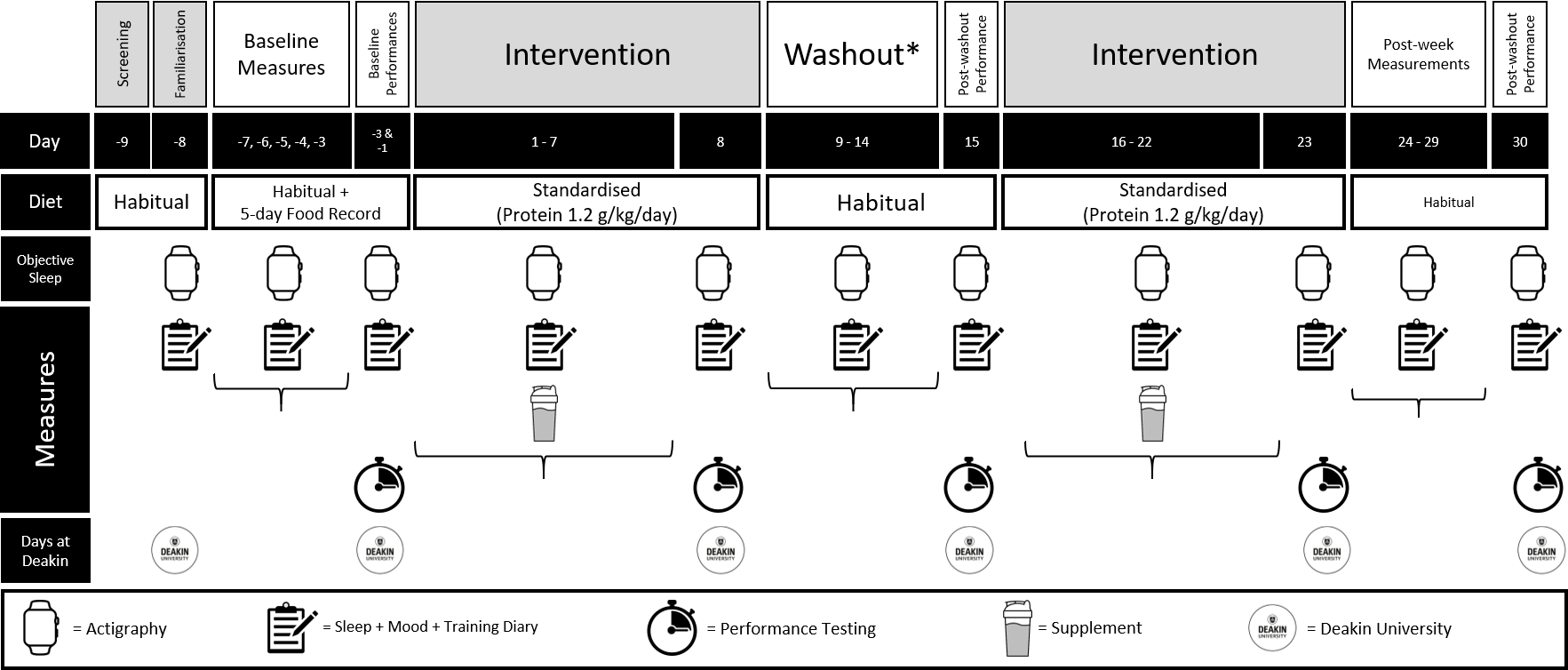
Menstrual phase will be determined by tracking of your menstrual cycle for two consecutive cycles prior to the study, during the study and for one cycle post-study.

## 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, mood, and performance. A graphic overview of the study is provided in Figure 1.

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

**Figure 1.** Graphic overview of the study. \*The washout period may be extended to ensure females commence the intervention period during specific menstrual phasing.



### Screening

Firstly, we will require you to complete a 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 the Deakin University Burwood campus to be given a tour of the sports science building. You will be given a briefing on the performance tasks that will be performed within this setting (i.e., Yo-Yo Intermittent Recovery Test Level 1, 30-second continuous jump test, and reaction time via Dynavision light board), which you will then perform a short run through. Basic anthropometry measures will also be taken during this session (i.e., height, weight).

### 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 individualised meal plans 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 wake 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).

Training will be monitored through a five-day training diary, which enables researchers to quantify your typical training loads and sessions. Training loads are a potential confounder to sleep, so this is required to be measured to ensure changes in sleep are related to dietary supplementation.

### Baseline Performances

Included in these baseline measures, are two lots of baseline performance testing days. This will require you to come to the Deakin Burwood campus twice at least one day apart, with the second baseline test to be completed one day before the first intervention period. Two baseline tests ensure your results are more accurate and less likely due to improvements through practice. These baseline performance measures will involve completion of the performance tests you would have had a brief run through at the familiarisation session (i.e., Yo-Yo Intermittent Recovery Test Level 1, 30-second continuous jump test, and reaction time via Dynavision light board).

Following the baseline testing, 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 group will receive 40 g collagen protein (Collagen Regenerate; Body Science, Burleigh, QLD) drink. Please note, you will be required to wear the non-invasive activity monitor for the entirety of the study for physical activity output and sleep measures to be recorded. This device should be only removed for water-based activities (e.g., showering, swimming).

### ***Day 1-7 (1st intervention period)***

During the experimental sessions, you will consume either the 40 g α-lactalbumin or placebo (40 g collagen) two hours prior to your ‘prescribed’ bedtime. You will be reminded to consume this supplement via text message at this time each night. Ninety-minutes post-supplement consumption (30 minutes before bedtime), three quick and simple questionnaires are to be completed that assesses your mood, recovery, and sleepiness. Sleep will be monitored through the activity monitor device that is to be always worn.

Thirty minutes upon rising, you are to complete these same basic questionnaires, in addition to a sleep diary that outlines measures such as subjective sleep quality. This will again be prompted via text messaging at the required time. Throughout each day, you are to fill out a training diary, and report training duration (min), exercise type and rating of perceived exertion for each session (or report that no training was completed). These measures allow for researchers to observe intensities of the training sessions, as well as potential exercise confounders between experimental periods.

### ***Day 8 (1st performance testing)***

Following one week of dietary supplementation, you will complete the same performance tests as performed at baseline (i.e., Yo-Yo Intermittent Recovery Test Level 1, 30-second continuous jump test, and reaction time via Dynavision light board), again within the Deakin Burwood sports-science building. These tests are to be completed at a previously agreed upon time, aiming to be within four hours of waking to limit confounding influences of increased drive due to body clock. Testing will commence with a 10-minute dynamic warmup, followed by the Yo-Yo Intermittent Recovery Test, 30 second continuous jump test, and reaction time. Recovery time will be given between activities, with the session to be completed within ~2 hours.

### ***Washout (days 9-14\*)***

Following the performance testing, the minimum 6-day washout period will begin. During this washout period, you can resume your habitual diet, with no placebo or α-lactalbumin to be consumed. For these immediate six days following the intervention period, you are to continue wearing the actigraphy device, and complete the sleep and training diary to observe any loading effect of α-lactalbumin supplementation.

\*Those athletes observing an extended washout period, need only to take these sleep measures for the immediate six days post each intervention period. Further, prescribed sleep/wake times are to be maintained for at least five days leading into the next intervention period.

### ***Post-washout performance (day 15)***

Following the immediate 6-days following supplementation, performance testing is once again to be completed at the Deakin Burwood campus. This is to investigate whether there is a continuing effect following cessation of α-lactalbumin supplementation on sleep, and whether this translates to improved performance. The performance testing will be completed as outlined previously (see Day 8).

### ***Day 16-22 (2nd 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)

### ***Day 23 (2nd performance testing)***

The 2nd performance testing methods will replicate the 1st performance testing day exactly.

### ***Post-week Measurements (days 24-29\*)***

The immediate six days following the second intervention period are to follow the same protocol as the initial washout.

### ***Post-week performance (day 30)***

Following these six days, performance testing is to be completed as per previous testing days (see Day 8).

### Living Conditions:

Throughout the intervention periods, you will remain in your usual environment, with all performance testing to be completed at the Deakin University Burwood campus. Throughout the intervention periods, you are to follow individualised meal plans provided by a sports dietitian, which will be matched to your habitual energy intake (as determined through your 5-day food record), with protein standardised to 1.2 g/kg/day. Protein intake is standardised as total daily protein intake may potentially influence sleep. Additionally, throughout the intervention periods, caffeine consumption and use of electronic devices (e.g., phone, iPad) in the evening is to be avoided. On the mornings of performance testing, no caffeine is to be consumed as this can influence performance.

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

### Study Measures:

* Height (cm), weight (kg), sleep difficulty score, PSQI score, chronotype
* Sleep outcomes via actigraphy (total sleep time, sleep latency, sleep efficiency, wake after sleep onset, fragmentation)
* 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
* Sports-related performance (i.e., Yo-Yo Intermittent Recovery Test Level 1, 30-second continuous jump test, and reaction time via Dynavision light board)
* Training output as measured through training diaries and activity monitor

### Participant Commitment:

* 1 screening session (can be completed via online teleconference)
* 5 days of baseline measurement (sleep, food record, and training diary)
* 7 visits to the Deakin University Burwood campus for familiarisation, and performance testing at baseline (×2), after each intervention periods (×2), and following both 6-day washout periods (×2)
* 7 days of supplementation × 2 (α-lactalbumin + placebo)

Time commitment each day of the intervention periods:

* total time taken to complete daily questionnaires and diaries is estimated at ~2 minutes.

Time commitment each day of performance measures:

* total time taken to complete warm-up, Yo-Yo Intermittent Recovery Test, 30-second continuous jump test, and reaction time testing is ~2 hours.

**5**. 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 may 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 Therapeutic Goods Administration. 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 an athlete 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 recovery, mood, and sports performance 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.

## 6. Possible Risks

There are few foreseeable risks throughout this study albeit minimal, including risks associated with exercise and food intolerance/allergies. Performance testing will be completed within the sports science gym (Deakin University, Burwood), which will be supervised to ensure your safety. Any food sensitivities or allergies should be disclosed, to ensure meal plans are tailored to your needs. Any lactose intolerance or dairy allergies will exclude you from participating in this study, as the α-lactalbumin is a dairy-based protein. 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 at a dosage of 40 g is not approved by the Therapeutic Goods Administration, given this dosage contains more than 100 mg of the amino acid tryptophan. This 40 g dosage has been used in multiple previous studies investigating athlete sleep, however, is still investigational in nature. Please note that the α-lactalbumin supplement used in this study has received Generally Regarded as Safe (GRAS) status 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.

## 7. 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.

## 8. 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, sports-related 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.

## 9. 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.

## 10. Payments to Participants

You will not be paid for your participation in the trial.

## 11. 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

## 12. 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).

## 13. 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 regularly throughout the intervention periods and once within the washout periods.

## 14. 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 on the sleep and performance of athletes with sleep difficulties within habitual environments

**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 on the sleep and performance of athletes with sleep difficulties within habitual environments

**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