PARTICIPANT INFORMATION SHEET

Study Title:	The CANnabidiol use for RElief of Short-Term insomnia (CAN-REST) A Randomised, Double-Blind, Placebo-Controlled Clinical Study
Short Title:	CanRest
Protocol Number:	BOD202101
Study Sponsor:	Bod Australia Ltd
Principal Investigator	Professor Ron Grunstein
Location(s)	Woolcock Institute of Medical Research

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research study because the answers you gave on the pre-screening questionnaire indicates that you have insomnia symptoms. This research study is testing whether cannabidiol (CBD) is safe and effective in reducing the symptoms of insomnia.

This Participant Information Sheet and Consent Form tells you about the research study. It explains what the study is about and what will happen. It also tells you about the risks and benefits of the study. Knowing what is involved will help you decide if you want to take part in the study. Before you decide if you want to take part, it is important that you read this information. Please ask the study doctors or staff to explain any words or procedures that you do not clearly understand. You may talk with your family, friends, and your general practitioner (GP) to help you make your decision. You can take as much time as you need to make this decision.

Participation in this research is voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. If you do not wish to take part, you do not have to.

This study will be delivered through online and telephone contact - there will be no face-to-face visits. If after your initial telephone consultation with the study doctor you decide you want to take part in the research study, you will be asked to give your consent electronically online. By completing it you are telling us that you:

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

This is an online, remote study conducted at the Woolcock Institute of Medical Research recruiting a total of 198 participants from within Australia.

2 What is the purpose of this research?

Insomnia symptoms occur in about a third of adults, affecting emotional, social and physical wellbeing. The current treatments include improving sleep habits, behaviour therapy, identifying and treating a possible underlying cause and sleep medications. Unfortunately, many of the sleep medications have potential dependency and abuse issues or other undesirable side effects. The *Cannabis sativa* plant consists of more than 100 different phytocannabinoids, with the most common being delta^{9}-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is primarily responsible for its intoxicating effects (feeling "stoned") whereas CBD does not possess any intoxicating effects and has been previously shown in clinical trials to offer a safe and effective alternative to combat insomnia symptoms.

The Therapeutic Goods Administration (TGA) that approves all medicines in Australia have, in principle, approved up to 150 mg per day CBD containing products to be supplied over the counter by a pharmacist, without a prescription (Schedule 3). However, there are currently no specific products yet approved to be accessed in this way.

The purpose of this study is to demonstrate how safe and effective CBD Isolate Softgel (Trade Name: Bod ECS BioAbsorb) is at reducing symptoms of insomnia compared with placebo. A placebo looks like and is packaged like the investigational drug but does not contain CBD active ingredient. The term "investigational drug" in this information sheet refers to both CBD and placebo. There is no THC component included in the investigational drug

The study is sponsored by Bod Australia Ltd and will be conducted under the TGA's Clinical Trials Notification (CTN) Scheme. This allows the investigators to use the investigational drug for medical research purposes.

3 What does participation in this research involve?

If you agree to participate in this study, you will be assessed for your suitability (screened) and if suitable you will be randomised (by chance, like the flip of a coin) to receive either 50mg CBD or 100mg CBD or placebo (in a 1:1:1 ratio) over an 8-week treatment period. This is a double-blind study. This means that, neither you, nor the study team, will know which study medication you are on (CBD 50mg, CBD 100mg or placebo). Your study doctor can find out in case of an emergency.

If you agree to participate, you will be asked to electronically sign the Consent Form as detailed below prior to any study procedures.

There will be a total of 5 telehealth appointments over approximately 14 weeks – screening, baseline week 4, week 8 and week 12.

Requirements and Restrictions

Birth Control

The effect of CBD and cannabinoids in general on your fertility, including future fertility, has not been investigated. The effects of CBD and other cannabinoids on the unborn child and on the newborn baby are not known. Because of this, participants must not participate in the research if pregnant, trying to become pregnant, breastfeeding, or planning ovum donation.

If you are female and child-bearing is a possibility, you will be required to undergo a serum pregnancy test prior to commencing the research project.

Both male and female participants are required to avoid pregnancy during the course of the research and for a period of 30 days after completion of the research project, as there is potential risk for an abnormal child being born. It is highly recommended that you inform your partner of your participation in the study and the need to avoid pregnancy. The study doctor will discuss effective methods of avoiding pregnancy with you.

Female participants - If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant. By signing this consent form you agree for the sponsor to monitor your pregnancy and the birth and the health of your child up to 30 days of age.

Male participants - You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary who will also provide you with an authorisation form to present to your partner. If she agrees, that authorisation will function as consent to approve the study doctor's access to medical information to allow monitoring of the pregnancy, and the birth and the health of the child up to 30 days of age.

Contraceptive methods

Together with your partner you must use two highly effective methods of contraception/birth control. Alternatively, you can practice true abstinence if this is in line with your preferred and usual lifestyle.
Examples of acceptable forms of highly effective contraception in fertile individuals include:

- established use of oral, injected or implanted hormonal methods of contraception
- placement of an intrauterine device (IUD) or intrauterine system (IUS)
- diaphragm, or cervical cap
- bilateral tubal occlusion
- condom
- sterilised male partner (with the appropriate post-vasectomy documentation of the absence of sperm in the ejaculate)

Examples of non-acceptable methods of contraception include:

- periodic abstinence (e.g., calendar, ovulation, symptothermal, post ovulation)
- withdrawal
- spermicide (as it is not approved as a method of contraception in Australia).

If you are uncertain of what form of contraception is acceptable for use during the study, then please ask your study doctor.

Medications

The following are **not permitted** during the study:

- **Sedatives** (e.g., benzodiazepines, Z drugs, agomelatine, suvorexant, sodium oxybate, sedating antidepressants, sedating antihistamines, antipsychotics, melatonin, valerian)
- **Opioids** (e.g., morphine, codeine, oxycodone, methadone, buprenorphine, fentanyl, tramadol, tapentadol, hydromorphone).
- **Stimulants** (e.g., methylphenidate, dexamphetamine, modafinil, phentermine, pseudoephedrine).

Caffeine and Alcohol – for duration of study

- Less than 600mg caffeine or approximately 6 cups of caffeinated beverages a day
- No more than four standard alcoholic drinks on any one day and no more than 10 standard alcoholic drinks per week

Study Procedures

Screening Assessment

You will have a telehealth appointment with a study researcher and study doctor to go through and answer any questions you may have on the study information. If you agree to participate you will be asked to electronically sign (e-sign) the consent. The doctor taking the consent will also e-sign the consent. The fully e-signed consent form will be emailed to you to keep for your records. Before consent is given you will verify your identity by showing a valid photo ID as will the study doctor taking consent. Once consent has been completed the study doctor will review and collect information from you as follows:

Demographics and Medical History

You will be asked to provide information regarding your gender, date of birth, race and ethnicity. The study doctor will also ask you about your physical and mental health and any illnesses and surgeries you may have had in the past.

Fasting Blood and Urine Tests – for safety and eligibility

- You will be provided with a Douglas Hanly Moir (DHM) request form via email and or post for you to take to a DHM collection centre convenient to you.
- Please do not eat or drink (except water) from midnight prior to having the blood draw
- A fasting blood sample (30mL or 2 tablespoons) will be collected from a vein in your arm using standard procedures, a process which takes approximately 10 minutes. Tests include biochemistry panel, full blood count, coagulation studies and where applicable a pregnancy test.
- A urine sample will also be required for safety urinalysis (pH, protein, glucose, and blood) and drug screening purposes.

- Additionally, a small sample of your blood and urine (5 mL or 1 teaspoon) will be sent to the Lambert Initiative Laboratory to analyse the possible effect of sleep disorders on biomarkers which may help us understand symptoms of insomnia better. In addition, to help understand the effectiveness of the CBD dose, the amount of CBD and its metabolic by-products in blood will be measured.

On-Study Assessments

The study doctor will review your blood and urine results. A member of the study team will contact you to discuss your eligibility to participate in the study. If you are eligible and you are happy to continue you will proceed as outlined below.

Telehealth Appointments (baseline, weeks 4, 8 and 12)

You will be contacted by study staff for a telehealth appointment and asked about your health and how you are feeling and if you have visited your GP or gone to hospital. This is done to ensure your safety during the study and to check if you are experiencing any side effects from the investigational drug. If you are, the study doctor will determine the best course of action for you.

During the telehealth appointment you will also be asked about any medication you are taking or have taken since previous contact (including over-the-counter medicine, or herbal supplements).

Each telehealth appointment should not take more than 30 minutes.

Actigraphy Device

During the study you will be asked to wear a diagnostic watch-like, wrist-worn actigraphy device to assess your insomnia symptoms. You will be asked to wear it continuously for seven consecutive days and nights on two occasions; before you start taking the investigational drug and then again after 7 weeks of taking the investigational drug. The device must be removed when washing or swimming. It will be posted to you at the address you provide. At the end of the seven days, you will be instructed to return the device immediately in the pre-paid postage satchel provided. A new device will be posted to you to use 1 week prior to completing the study drug.

You will be given additional verbal and written instructions by the research staff.

Sleep Diary

You will be required to complete a short online, 5-minute sleep diary on 3 occasions; each occasion will be for 7 consecutive mornings:

- 1 week before you start taking the investigational drug at the same time as you wear the actigraphy device.
- After 3 weeks of taking the investigational drug.
- After 7 weeks of taking the investigational drug at the same time as you wear the actigraphy device.

Questionnaires

You will receive an email with a link to online questionnaires regarding changes in your sleep, mood, and general health. These should take about 30-60 minutes to complete.

You will be required to complete these three times during the study. Once at baseline before you start taking the investigational drug, after 4 weeks and again when you have finished taking the investigational drug.

Investigational Drug

Once the online questionnaires are completed at baseline sufficient investigational drug for the 8-week treatment period will be sent to the address you provide. The study team will then instruct you when to commence taking four capsules approximately 2 hours before bedtime each night. Instructions for how to take your study medication will be provided on the packaging. You are to avoid driving or operating machinery after you take the study drug before going to bed. You will also be provided with a Dosing Diary for you to record daily that you have taken the study drug or if you have missed a dose with an opportunity to give a reason for missing the dose.

Please keep all the used blister packaging as these, along with any untaken capsules must be returned at the end of the study with the completed Dosing Diary. A pre-paid postage satchel will be provided for this purpose.

Fasting Blood and Urine Tests – safety and CBD metabolites

As described in screening section, a fasting blood and urine sample will be required during your last week of taking the investigational drug, i.e., during the second time you wear the actigraphy device. . Where applicable, you will be asked to complete a urine pregnancy test between week 9-10, once you have finished taking the investigational product; a urine pregnancy test will be posted to you for this purpose.

Quick Reference Table of Assessments schedule

Screening	Telehealth; Informed Consent; Demographics and Medical History; Medications; Caffeine and Alcohol restrictions; Fasting Blood/Urine Tests
Baseline	Telehealth; Actigraphy Device; Sleep Diary; Questionnaires
Week 4	Telehealth; Sleep Diary; Questionnaires
Week 7	Actigraphy Device, Fasting Blood /Urine Tests
Week 8	Telehealth; ; Sleep Diary; Questionnaires; urine pregnancy test at week 9-10, where applicable.
Week 12	Telehealth to follow-up on your well-being

4 What do I have to do?

Before you decide whether to be in this study, you should think about how the tests and study requirements will affect your time.

To be in this study you must agree to:

- Follow directions from study staff
- Keep study appointments
- Make every effort to take the investigational drug as instructed
- Give blood and urine samples
- Tell the study staff about all of the medicines you take or stop taking during the study
- Tell the study staff about any changes to your health during the study
- Not be part of any other research study while participating in this study without first talking to the study staff.

5 Additional Costs

There are no additional costs associated with participating in this research project. All medical tests, medical care required as part of the research project and investigational product will be provided to you free of charge.

6 Remuneration and Reimbursement

You will be provided with a $400 voucher on completion of the study at week 12 as financial remuneration for your time and to cover any travel costs incurred to attend DHM collection centre. Should you discontinue the study after week 4 and prior to week 8 you will receive $100 voucher. If you discontinue after week 8 and before week 12 you will receive $200 voucher.

7 Other relevant information about the research project

A description of this clinical trial will be available on clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results.

8 Do I have to take part in this research project?

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage and you do not have to give a reason. This will not affect your future medical care in any way.

If you do decide to take part, you will be given this Participant Information and Consent Form to electronically sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Woolcock Institute of Medical Research.

9 What are the alternatives to participation?

You do not have to take part in this study to receive treatment for your condition. If you decide not to take part in this study, you are encouraged to consult your GP to discuss treatment options available. Additional information can be found here: Sleep Health Foundation. You also have the right to withdraw from the study at any time and for any reason.

10 What are the possible benefits of taking part?

Your symptoms of insomnia may improve while you take part in this study. It is possible that there will be no direct benefit to you from taking part, however, this study may help us to understand whether this formulation of CBD is safe and effective. The information from this research might benefit others in the future.

11 What are the possible risks and disadvantages of taking part?

Investigational Drug

Medical treatments often cause side effects. You may have none, some or all the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the study doctor. Your study doctor will also be looking out for side effects.

CBD produces mostly mild side effects that appear to resolve with time. The most commonly experienced adverse effects are somnolence (sleepiness or drowsiness) (36% or 36 in 100), diarrhoea (31% or 31 in 100), decreased appetite (28% or 28 in 100), fatigue (20% or 20 in 100).

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Your insomnia symptoms may not improve and could worsen even if you take part in this study regardless of what study medication group (CBD or Placebo) you are assigned to.

There may be some side effects that are not yet known. You may or may not experience any side effects related to the investigational drug. If you do, the extent to which they occur can vary. Some of these side effects can be mild, moderate or severe.

For this reason, all study participants are monitored closely by the research doctor and team. If you experience side effects, your study doctor will determine the best course of action for you which may include taking you off the study medication to ensure your safety and wellbeing.

In addition to the risks or discomforts listed here, there may be other risks that are currently not known. Also, the risks or discomforts described may occur more often or be more severe than have been seen before.

To protect your safety a separate group of specialist medical doctors and experts will review the results of study procedures and your progress during the course of this study. This group can make special recommendations to ensure that patient safety is protected throughout this study.

Allergic Reaction Risks

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some signs that you may be having an allergic reaction are:

- Rash or hives
- Having a hard time breathing
- Wheezing when you breathe
- Sudden change in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study. For urgent assistance please call 000.

Some of the study activities involved may cause some side effects. You may have none, some or all of the effects (listed below), and they may be mild, moderate or severe.

Actigraphy

Actigraphy has for some time been used clinically across a number of patient populations with minimal to no reported risks or side effects. If you have sensitive skin, you may develop a rash/skin irritation or may experience some discomfort from the wrist strap materials.

Blood draws
Some known risks, although rare, are associated with placing a needle into a vein or under the skin. You may have pain, swelling, or bruising where the needle enters your vein. There may be risk of infection. You may feel dizzy or may faint.

12 What will happen to my test samples?

The collected blood and urine samples will not be stored on site at the Woolcock Institute of Medical Research. All but a small sample of blood and urine will be destroyed in accordance with DHM policies and procedures. The small sample of retained blood and urine will be safely and securely stored at the central DHM laboratory and will be safely transferred to The Lambert Initiative Laboratory, Sydney, at the end of the study.

These retained samples will be tested for the concentrations of the active medication being given in the trial (CBD) and its metabolic by-products. This will allow the investigators to understand whether the medication is being adequately absorbed into your bloodstream. Additionally, these samples will be used to explore how the medication affects various molecules known as “endocannabinoids”. These are naturally occurring cannabis-like molecules that naturally exist within your brain and body which influence sleep, appetite and mood. We are interested to learn whether CBD influences various endocannabinoids and whether this might relate to a beneficial effect on sleep.

The retained samples will be destroyed in accordance with The Lambert Initiative procedures and policies.

All test samples taken will be labelled with a unique code. The results will be kept confidential by the study doctor; however, if the standard test results are clinically relevant the study doctor will discuss these with you and your GP, if appropriate.

13 What if new information arises during this research project?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want to continue in the research study. If you decide to withdraw, the study doctor will encourage you to consult your GP. If you decide to continue in the research study, you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in your best interests to withdraw you from the research study. If this happens, he/ she will explain the reasons and encourage you to consult your GP.

14 Can I have other treatments during this research project?

There are a number of medications that are not permitted during the study. Whilst you are participating in this research study, you may only continue to take your regular medications or treatments as agreed with the study doctor during the screening telephone consult. It is important to tell the study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

You should also tell the study team about any changes to these during your participation in the research study.

15 What if I withdraw from this research project?

If you wish to withdraw from the study, please advise a member of the study team. Any health risks or special requirements linked to withdrawing will be discussed with you.

If you do withdraw during the study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the study results. If you do not want them to do this, you should not participate in this study.

16 Could this research project be stopped unexpectedly?

Your doctor or the sponsor may withdraw you from the study without your consent for the following reasons:

- if you have a side effect from the study drug,
- if you need a treatment not allowed in this study,
- if you do not follow the study procedures as instructed,
- if you become pregnant, or
- if the study is cancelled by the regulatory authorities or the sponsor.

17 What happens when the research project ends?

Continued access to the study drug after completion of the trial will not be available to any participant.

We advise you to seek guidance from your GP about future management of your insomnia symptoms when:

- You complete the study, or,
- You leave the study early.

Part 2 How is the research project being conducted?

20 What will happen to information about me?

By completing the consent form, you agree to the study doctor and relevant research staff collecting and using personal information about you for this study. Any information obtained in connection with this study that can identify you will remain confidential. There is a risk of loss of confidentiality in research studies. Every effort will be made to protect you and your health information to the extent possible. The information collected about you will be anonymous to protect your identity and your name will be removed and replaced with a unique code (“key-coded data”).

Your personal information (name, date of birth and contact details) and pre-screening questionnaire answers will be captured and stored on a database called SPARDAC. This is a secure web-based database developed and maintained by the Wappsystem Pty Ltd. The secure server is located at Amazon Web Services in Sydney, NSW. (https://docs.aws.amazon.com/whitepapers/latest/aws-overview/security-and-compliance.html). Access is provided via the user's institutional login credentials and is managed by the Principal Investigator through the User Rights setting for the Spardac project. Within this network, files are restricted to researchers and cannot be accessed without password permissions

The electronic Consent and access for you to complete online questionnaires will be implemented in a system provided by the company IBM: Study staff will activate your access to the system. A unique and auto-generated User ID will be assigned to you and will be sent to your email address. You can use this unique ID number to log in for the first time and change your password. You can review the study information and e-sign the consent form and can answer the online questionnaires after the informed consent is signed using your login details. The e-signed consent forms and your personally identifiable information and clinical study data are encrypted and stored in separate servers in IBM facilities in North Carolina, USA. Information you provide us will be recorded in special electronic forms and will be coded by your unique study number, and thus will be considered re-identifiable. The information from these forms will be added to a computerised database managed by the sponsor and will be part of the study results, which may be published. This database will be protected and accessed by individual user password.

A copy of these forms and your study medical record will be kept for at least 15 years with all other study related documents.

Your information will only be used for the purpose of this research, and it will only be disclosed with your permission, except as required by law. Information about you may be obtained from your health records held at this and other health services for the purpose of this research. Your de-identified data may be shared with other local or international collaborators and used for future research purposes; however, Human Research Ethics Committee (HREC) approval will be sought prior to any future use of the data.

By completing the consent form, you also agree to the study team accessing health records if they are relevant to your participation in this study.

Your study records may be reviewed by:

- BOD Australia Ltd - the study sponsor
- People who work with the sponsor on the study
- Government agencies, such as the Australian Therapeutic Goods Administration (TGA)
- Bellberry HREC, a group that reviews and approves research studies,
- Woolcock Institute of Medical Research

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law. Your data may be shared with other collaborators who provide a methodologically sound proposal and sign a data access agreement. By completing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. The information provided to the study sponsor will not identify you and therefore you will not be individually identified in any publication of study results.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or state/territory privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

21 Compensation for injury/ what if something goes wrong?

If you suffer any injuries or complications as a result of participating in this study, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment as a public patient in any Australian public hospital free of charge. You do not give up any legal right to take legal action to obtain compensation for any injuries or complications resulting from the study.

If you are injured as a result of your participation in this trial, you may be entitled to compensation. There are two avenues that may be available to you to seek compensation.

1) Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors. However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines. These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Policy – Clinical Trials – Indemnity and Compensation Guidelines. Alternatively, your study doctor can provide you with a hard copy of the guidelines.

2) You may be able to seek compensation through the courts.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

22 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by Bellberry HREC in accordance with the *National Statement on Ethical Conduct in Human Research (2007, incorporating all updates)*. This statement has been developed to protect the interests of people who agree to participate in human research studies

23 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the study doctor on 02 9114 0438 or any of the following people:

Study contact person

Name	Study Co-ordinator for CANREST Study
Telephone	02 9114 0469
Email	canrest@woolcock.org.au

Reviewing HREC approving this research and HREC Executive Officer details

Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact:

Reviewing HREC name	Bellberry Human Research Ethics Committee
HREC Executive Officer	Operations Manager
Telephone	08 8361 3222
Email	bellberry@bellberry.com.au
Protocol No.	BOD202101

Research Governance Officer

The conduct of this study has been authorised by the Woolcock Institute of Medical Research, any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer:

contact

Name	Grigori Kaplan
Position	Governance Officer
Telephone	02 9114 0412
Email	Grigori.kaplan@sydney.edu.au

This information is for you to keep.

ONLINE PARTICIPANT CONSENT FORM

Study Title:	**The CANnabidiol use for REIief of Short-Term insomnia (CAN-REST) A Randomised, Double-Blind, Placebo-Controlled Clinical Study**
Short Title:	CAN-REST Study
Protocol Number:	BOD202101
Study Sponsor:	BOD Australia Ltd
Principal Investigator	Prof Ron Grunstein
Location(s)	Woolcock Institute of Medical Research

Declaration by Participant

I am aged between 18-65 years
I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
I understand the purposes, procedures and risks/benefits of the research described in the project.
I understand that my participation in this study will allow the researchers to have access to my medical record, and I agree to this.
I give permission for my doctors, other health professionals, hospitals or laboratories outside this study site to release information to The Woolcock Institute of Medical Research concerning my health and treatment for the purposes of this project. I understand that such information will remain confidential.
I have had an opportunity to ask questions and I am satisfied with the answers I have received.
I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the study doctor during the conduct of the trial, if applicable.
I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.
I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without penalty or giving a reason by advising the study team. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw will be stored and analysed.
I understand the study team will manage the e-consent form database and have access to this Consent Form, which will be stored on the IBM facilities in North Carolina, USA.
I understand that this electronically signed consent form will be emailed to me to keep.

Name of Participant

Participant e-mail address

[electronic signature here] [electronic date stamped]

Declaration by Study Investigator

I have given a verbal explanation of the research project, it's procedures and risks and I believe that the participant has understood that explanation.

Name of Study Investigator

[electronic signature here] [electronic date stamped