Clinical Trials Unit
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MACQUARIE University
SYDNEY·AUSTRALIA

Participant Study Summary

Title	A Double-Blind Randomised Controlled Trial of Microdosing with Psilocybin to treat Moderate Depression
Protocol #	MICRODEP-01
Chief Principal Investigator Name & Title	Dr Vince Polito
Location	Macquarie University

You are invited to participate in the above research study because *you have been deemed preliminarily eligible following a pre-screening assessment.*

This study aims to find out how safe, tolerable and effective *a new treatment called WP001 is in cases of moderate depression*.

WP001 is a synthetic form of the naturally occurring compound psilocybin, which is what gives psychedelic mushrooms their psychoactive effects. In this trial, we are examining whether low, sub-hallucinogenic doses of synthetic psilocybin may be effective in treating depression. Participants will be randomly allocated to either an active placebo (caffeine) or WP001 condition in a 1:1 ratio. If you are allocated to the WP001 condition you will be given a dose approximately 5-10x smaller than a traditional psychedelic dose of psilocybin. Individuals vary considerably in their response to psilocybin. At this dose range most people are able to perform their normal day to day activities. Some individuals do not notice any drug effects at all. You may experience minor perceptual effects or slight changes in mood and emotional state. Sometimes people report more prominent effects and these can be both pleasant and unpleasant. For example, you might feel improved concentration or more easily distracted; improved mental clarity or slightly confused; more sociable and energised or prefer to focus on individual activities; more engaged with things in your life or somewhat unmotivated; a greater sense of calm or a sense of anxiousness. In rare cases, some individuals may perceive stronger effects and find the effects disorienting. Your specific reaction, or whether you feel anything at all, is difficult to predict. Because of this, we ask participants to enter the experience with an open mind and to avoid expectations around particular experiences. We do not anticipate any major negative psychological or physiological side effects. Psilocybin is a non-toxic, non-addictive drug that is very safe when consumed responsibly with good clinical practice. As we are administering low doses, it is very unlikely you will experience any of the acute negative psychological experiences associated with having a “bad trip”. You may experience some minor physical effects such as headache, elevated heart rate, changes to your appetite, drowsiness or yawning, or nausea. There will always be a welcoming, comfortable atmosphere at the site you visit to receive your dose and a trained individual to speak to if needed.

For a full description of the purpose and rationale for this research see Sections 2 and 3 of the main information sheet.

The study is sponsored in Australia by Macquarie University and is being conducted at Macquarie University under Chief Principal Investigator Dr Vince Polito.

About 266 participants are expected to participate in this research project at Macquarie University.

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Participation in this study is voluntary. If you decide not to participate or you decide to withdraw from the study at a later stage, it will not affect your relationship with the research team or the institution, Macquarie University.

If you consent to take part and you are eligible to participate in this study, you will need to attend the clinic at least twice a week for 6 weeks. During these visits you will answer questionnaires and have blood tests and other assessments. The schedule for study visits and a full list of all tests and procedures is in section 3 of the main consent form. After the study treatment has finished you will be required to visit the site on two additional occasions, 1 week after the study completes and one month after the study completes. You will also be asked to complete an online survey 3 months and 6 months after completion of the study.

There can be no certainty that you will have any benefit from the intervention in this study. The knowledge gained from this research project may be of help to treat patients with your condition in the future. You will not be paid for taking part in this study. However, we will cover transport costs associated with the study and you may have meals covered on the days that you need to stay longer on site.

While on the study and receiving treatment, you may experience side effects, *please refer to section **9.** of the Main Consent form* regarding the known risks of participating in this study. There may be other side effects or risks that are not known at this time. Additionally, there may be risks to breast-fed infants or to an unborn child carried by female participants (or partners). If you or your female partner becomes pregnant during your participation in the study, you need to inform the study doctor immediately.

Additional information about what data will be collected about you during the study, how that data will be used and your privacy protected can be found in sections 13 and 14 of the main consent form. Additional information regarding compensation, funding, complaints and who to contact can be found in sections 15-21 of the main consent form.

Please make sure you have completely understood what the study involves before you decide to participate.

Dr. Vince Polito

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Participant Information Sheet

Trial Title:	A Double-Blind Randomised Controlled Trial of Microdosing with Psilocybin to treat Moderate Depression
Protocol Number:	MICRODEP-01
Chief Principal Investigator Name & Title:	Dr Vince Polito
Sponsor | Institution | Location :	Macquarie University

1 Would you like to take part in this clinical study?

We would like to invite you to take part in our clinical study. This is because you have moderate depression and have passed the pre-screening stage.

This document tells you about the study and describes what will happen if you take part. If there is anything you don't understand or want to know more about, please ask us.

If you don't know what to ask, there are some questions to consider in the *Clinical study participant information and consent form: Part A – General information*.

You might also want to talk to a relative, a friend or your GP before you make up your mind. You may also take this form away with you. If you decide to go ahead, we will ask you to sign the consent form (*the last page of this document*).

2 Why are we doing this research?

The purpose of this study is to assess how effective a new potential treatment called WP001 is in treating depression.

WP001 is a synthetic form of the naturally occurring compound psilocybin, which is what gives psychedelic mushrooms their psychoactive effects. It works by stimulating serotonin receptors in the brain. It has a very low risk profile, does not lead to addiction or dependency and is not associated with any long-term health deficits. The dose we are administering in this trial is very low compared to previous studies of psilocybin. The study drug is WP001 is experimental meaning that it has not been approved by the TGA for use outside of a clinical trial or research setting. WP001 has not been approved to treat depression or any other indication in Australia.

We are conducting this trial to explore whether a six week intervention, with regular doses of WP001 might reduce symptoms of depression.

3 What is involved in the study?

We expect to recruit around 266 participants at Macquarie University.

<u>Screening session</u>

During this first session, you will be screened by a psychiatrist to ensure safety and eligibility. If you make it through to the next stage, we will begin the trial a maximum of four weeks from now. It is important you start at an appropriate time, decided on after taking any other obligations into account. Once you begin, the drug intervention will last 6 weeks and there will be occasional follow up sessions for 8 months. The psychiatric screening will take up to 2.5 hours.

<u>Physical screening</u>

Following approval by the psychiatrist, you will be asked to come to Macquarie University to have some screening measures administered in person. This will involve various non-invasive measures, including an ECG recording to assess your heart health, and one invasive procedure, providing a small blood sample to ensure there are no irregularities. If you meet our safety standards for these measures, you will be invited to come back for formal baseline measures. At this point, you will have completed screening. However, you will not be invited to take part in the intervention until your responses to baseline measures have been assessed. The physical screening will take approximately one hour.

The screening session with the psychiatrist and physical screening may be combined into one visit.

Baseline Measures

During the baseline phase we will conduct a series of psychological assessments of mental health, wellbeing, personality, beliefs and attitudes. A total of 28 tests will be administered as questionnaires and computer based tasks. We will also take a blood sample. This session may take up to three hours. Following analysis of baseline responses, you may be invited to take part in the intervention.

Intervention

If you are invited to this stage, you will be randomised to a study condition and the trial will begin.

You will have a 50% chance of being given one of the following treatments:

- 4mg of psilocybin (active drug)
- 60mg of caffeine (active placebo)

Doses may be reduced at investigator discretion. Whichever treatment you're assigned to, this will involve taking up to 4 capsules each dosing session.

To avoid accidentally influencing the results of the trial, neither you nor the researchers will know whether you received the placebo or a dose of active drug. This is known as "double blinding". However, if it is necessary for your care, researchers will "break the blind" and find out what substance you have been given.

After we have completed recruitment for the study, we will run preliminary analyses to determine whether there is evidence that the active drug is effective in treating depression. If we find evidence of efficacy, we will then offer participants who received the active placebo (caffeine) the opportunity to try the intervention with psilocybin. In other words, participants in the placebo condition will later be offered a chance to try the active drug if we find it is effective.

The drug treatment will go for six weeks and you will be required to come to Macquarie University twice each week. On each study visit, you will receive a dose of a study drug (either the active drug or active placebo). You will also be asked to complete questionnaire and computer based measures of mood, mental health, cognition and subjective experience. A range of 2 to 29 tests will be administered as questionnaires and computer based tasks depending on the visit. On days you receive a dose, you will also complete questionnaires at home about your experience. A range of 2 to 4 tests will be emailed to you depending on the visit. During weeks one, three and six we will also take a blood sample.

Your first dosing session will include a period of safety monitoring and you will be required to stay at the university for four hours. During the first visit you may be asked to provide blood samples on 8 occasions throughout the session. We will use an IV canula to take small samples (2ml) at the start of session and then again at 15 min, 30min, 45min, 60min, 120min, 180min, and 240min.

One visit each week will be relatively short (approximately 15 minutes). The other visit each week will involve additional tests and will last up to 90 minutes.

After your dosing session in weeks one and six, we may conduct an interview to ask you about your subjective experiences of any drug effects. These interviews will take an additional 60 minutes.

The drug treatment will end during week six. The final visit during week six will be a longer session with a battery of questionnaires and computer based tasks. This session may take up to three hours.

FollowUp Visits

You will be required to attend two follow up visits at Macquarie University: one week after the intervention ends, and one month after the intervention ends. These visits will involve a series of questionnaire and computer based tasks and may take up to three hours. We will also take a blood sample during these visits.

Finally, you will be required to complete online followup visits 3 months after completing the intervention and 6 months after completing the intervention. These will consist of questionnaire and computer based tasks and will take up to 90 minutes to complete.

Open Label Extension Stage

After all participants have completed the main study, we will seek to run an open label extension of the study if clinical efficacy is established. This would allow participants allocated to the placebo condition who remained in the study for the complete intervention the opportunity to receive the active drug (psilocybin). This study will run contingent on funding and approval.

If you are allocated to the placebo condition, would you like to be contacted and offered the opportunity to participate?

☐ YES

☐ NO

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	Pre-Screening and Screening			Baseline	Treatment											EoT	Follow Up			
Assessment / Measure Name	**PreScreening (SelfReport Questionnaire)**	**Screening (Psychiatric)**	**Screening (Safety)**	**Baseline**	**Wk 1A**	**Wk 1B**	**Wk 2A**	**Wk 2B**	**Wk 3A**	**Wk 3B**	**Wk 4A**	**Wk 4B**	**Wk 5A**	**Wk 5B**	**Wk 6A**	**Wk 6B**	**1Wk Follow Up**	**1M Follow Up**	**3M Follow Up**	**6M Follow Up**
ESTIMATED VISIT DURATION (mins)	33	146	65	122	270	75 / 135	16	63	16	75	16	63	16	75	49 / 109	158	126	121	82	82
Formal consent	X	X																		
Review your health History		X																		
Review your medication History	X																			
Prescreening Questions	X																			
Questionnaires	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review side effects and any changes since last visit					X	X	X	X	X	X	X	X	X	X	X	X	X	X		
ECG			X																	
Blood Sample – Safety			X							X										
Blood Sample - Biomarkers				X	X					X						X	X	X		
Take study drug					X	X	X	X	X	X	X	X	X	X	X					
Driving simulator			X			X								X						
Computer/Activity based task						X		X		X		X		X						
Qualitative interview						X									X					

4 What are my responsibilities during the study?

If you agree to participate in this study, you agree to the below:

- Following instructions and guidance provided by the trial staff, attend all scheduled study visits, and be available for any scheduled telephone visits
- To be responsible for taking the study drugs according to our instructions.
- You are not allowed to take certain medications while in this study. If you decide to begin a new medication, please discuss it with your study doctor first.
- Tell your trial doctor and/or trial staff if you change medications or start new ones. This includes all prescription and over-the-counter drugs, herbal preparations, and food supplements that you are taking or planning to take
- While participating in this trial, you should not take part in another clinical trial.
- Tell your trial doctor and/or trial staff about any experiences, symptoms, side effects or changes you may have had and noticed. Even if you think that it has nothing to do with this trial or the study drug as it is important that we record any adverse events that you have experienced.
- Not to start any new psychotherapies, medical interventions or alternative therapies to treat mental health during the trial.
- If you are treated by another doctor, it is important that you tell the trial staff about your treatment and what happened.
- Nominate a friend or family member who will agree to support you during the trial.
- Don't operate machinery 3 hrs after dosing. This means you cannot drive to or from any study sessions. We will provide transport to and from the site for all study visits.
- Complete a report and some questionnaires via a link sent to your email after each dosing session.

You will receive a Participant Card. This card has information on the trial and contact details. You should always carry this card with you. If you are treated by another doctor, for example, in an emergency, show them this card. It is important that they know that you take part in a clinical trial. Additionally, you also agree to comply with the other conditions in this document. If you cannot, or do not wish to accept this responsibility, then we cannot accept you as a participant in the study.

To take part in this study you must nominate a Support Person who agrees to assist you with your participation in the trial. We will contact this person as a backup if we cannot reach you for any reason or if we are concerned about your physical or mental health.

5 Will you pay me to participate in this study?

There is no reimbursement or payment for this study. However, we will cover transport costs to and from Macquarie University. We will also provide meals during long study visits.

All treatment, medication and study-related tests will be provided at no cost to you.

6 Do I have to take part?

Taking part in this study is entirely voluntary. If you don't wish to take part in the clinical study, you don't have to. There are approved treatments that are available to treat depression and you may want to consider these before deciding to take part in this trial. The intervention in the current trial is experimental and may or may not benefit from taking part.

If you decide to take part and later change your mind, you are free to withdraw at any stage.

We must keep any information we collect about you, up until you withdraw. The institution conducting the study, has access to this information so they can check it is correct. If you do not agree with this, then we cannot allow you to join the clinical study.

When your participation ends, no new health information will be collected about you. However, the research team will still be able to use any health information about you that has already been collected during this study up until the point that you withdraw. When your participation ends, no new information will be collected about you with two exceptions:

1) any laboratory samples collected prior to stopping may still be tested, unless you specifically ask for your samples to be destroyed, and
2) in the case where you withdraw from treatment or are withdrawn from treatment and you agree to continue to have follow up visits and assessments and agree to have the study team contact you to follow up on your health.

7 Can I have other medicines or procedures during this clinical study?

You may continue with any ongoing therapies or treatments after confirming with the study investigator. However, after taking part in the study, you should **not start** any new treatments or therapies without discussing this with the study investigator as well as your health practitioner.

You must tell us about any procedures or medicines you may be using. This is in your interest as well as important for the study because they may interfere with the treatment and aims of the study. You must tell us about any prescription or over-the-counter medications, vitamins or herbal remedies you are taking. You must tell us if you are having other alternative procedures (for example, osteopathy, chiropractic, dietetics, acupuncture). You must also tell us about any changes to these while you are participating in the clinical study.

8 What possible benefits might I get by taking part?

We cannot promise you any personal benefits from this research. It is possible that your condition may improve but it can also worsen. You may benefit from the more frequent review of your condition during the study.

By taking part, the information gained from your participation may be helping other people with depression in the future as well as help researchers learn more about the study drug.

9 What risks do I run by taking part?

Medical procedures, medicine and tests often have side effects. You may have no side effects, some, or all of the side effects listed below. These side effects may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may also 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 the intervention 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 procedure. Your study doctor will discuss the best way of managing any side effects with you. Some unwanted effects may actually not be related to the study, nevertheless it is important to document these.

The participants in trials receiving standard doses (25 to 30 mg) of psilocybin reported the following side effects:

- Anxiety
- Confusion
- Paranoia
- Psychotic phenomena
- Dizziness
- Nausea
- Abdominal pain
- Tremors
- Loss of appetite
- Muscle aches or weakness
- Restlessness
- Sleep disturbances
- Coordination impairments
- Working memory impairments
- Headache
- Physical discomfort (“body load”)
- Persisting perceptual effects

However, it is important to note your dose will be approximately 5-10x lower than most previous trials, so the risk of side effect is diminished. The most common side effects reported following low doses of psilocybin are:

- Headache
- Heightened negative emotions
- Sleep disturbances
- Distractibility
- Anxiety
- Nausea

There are also some side effects that have been reported following doses of the active placebo (caffeine):

- Restlessness and shakiness
- Insomnia
- Headache
- Dizziness
- Increased blood pressure

- Dehydration
- Anxiety

Certain study procedures also carry small risk. As part of your participation in this clinical trial, you agree to have your blood sample drawn at various timepoints. Though your blood samples will be taken by trained staff, you may experience the following complications:

- Discomfort or pain due to swelling or bruising around the injection site
- Redness at the needle insertion site
- Light-headedness and fainting (uncommon)
- Very small risk of infection at the injection site

If you experience any of these side effects, or any other untoward medical occurrences during the trial you should report this to one of the staff or investigators.

To maximise safety, you must agree not to undertake any tasks that require a high level of concentration or coordination and not to operate any vehicles or any heavy machinery for 3 hours after taking the study medication. We recommend that you refrain from these activities entirely on dosing days.

10 How will you use any tissues or samples you take from me?

If you agree to participate in this study, we will take some safety and biomarker blood samples that we will use and/or store for testing in this study.

The bloods samples will be used to review your health and to learn more about the study drug.

Agreeing to taking part in this study means you agree to have your blood samples collected at:

- Screening,
- Baseline,
- Week 1A (first 25 participants only),
- Week 3A,
- Week 6B,
- 1 Week Follow Up and
- 1 Month Follow Up

Although there has been increasing scientific interest in the cognitive and psychological effects of microdosing psychedelics in recent years, we still do not know very much about the physiological effects of microdosing. Preliminary research indicates that a range of blood based biomarkers (i.e., proteins, enzymes and metabolites) may be sensitive indicators of the neurogenerative effects of serotonergic psychedelics.

During the study you will be invited to provide a blood sample. This will take place in our clinic at Macquarie University. We will analyse the sample for potential biomarkers that may reveal the effects of microdosing.

Specifically, we will conduct the following tests:

- Typtophan metabolite analysis (Tryptophan, kynurenine, kynureninc acid, 3OH -Kynurenine, Anthranilic acid, Quinolonic acid, picolinic acid, neopterin, serotonin, melatonin) and NAD metabolites.

- Multiplex cytokine array, which tests the following proteins: GM-CSF, IFNγ, IL-1β, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12(p70), IL-13, MCP-1, TNFα.
- Enzyme-Linked Immunosorbent Assay (ELISA) analysis of Brain-derived neurotrophic factor (BNDF), Glial cell line-derived neurotrophic factor (GNDF), cortisol and c-reactive protein
- Genetic analyses of BDNF and kynurenine pathways.
- Analysis of psilocin, psilocybin, and psilocin-glucuronide levels in blood plasma.

Samples will be stored at the Macquarie University Biobank. Biosamples will be identified using your unique participant identification code and not routinely linked to any identifiable information.

Analyses will mainly be analysed at Macquarie University, however deidentified samples for the multiplex cytokine array test will be sent to Eve Technologies in Calgary, Canada. This is a commercial biomedical lab that has the most effective assay technology for these tests.

By consenting to this study you agree, samples may also be analysed in future research related to microdosing and/or unspecified research.

This research aims to understand the potential Neurogenerative effects of psilocybin and is not primarily a genetics study. No information is likely to be revealed that would be important to your health. There are no anticipated commercial applications or outcomes from this research.

You will not obtain the results of these tests. This type of testing is done to further our knowledge about how the study drug works and it will not produce the type of results that will have any useful meaning that would affect your health or treatment.

11 What if something new comes up during the study?

If we find something new about an intervention while the study is under way, the study doctor will discuss with you what it means and whether you want to continue in the study. If you decide to continue in the clinical study, we will ask you to sign an updated consent form.

12 What will happen to the confidential information about me?

We will keep all personal information confidential and securely stored.

No personal information about you, such as your name and address will leave the clinic, and in all study information sent out from the clinic, you will be identified with a code number only.

The study funder (Woke Pharmaceuticals) will receive a copy of non-identifiable study data. Your health records and any personal information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor and institution relevant to this Consent Form, Macquarie University, or as required by law. By signing this Consent Form, you authorise release of, or access to, this confidential information to (and use by) such parties and regulatory authorities.

13 What information will be collected, and how will it be stored?

Australian and New South Wales privacy law gives you the right to request access to your information that the researchers have collected and stored. The law also gives you the right to request corrections to any information about you that you disagree with. Please contact the study team (see section 19 of this document) if you would like to access your information.

We will not disclose your information without your permission, except in compliance with the law. Information about you may be obtained from your health records held at this institution and may be

obtained from other health services for the purposes of research. Should you wish to cease treatment we would like the option to maintain follow up. If you sign the consent form, you agree to the study team accessing health records if they are relevant to your participation in this study.

You may be asked to take part in up to two interviews during the study. Audio from interviews will be recorded for the purpose of transcription and stored digitally. After transcription, audio files will be permanently deleted to protect your privacy.

The data collected and required for this study will be stored securely on an online database that can only be access by a limited number of authorised personnel. Any data that is stored in the database will be coded and will not identify you directly; your data set will be linked to your uniquely assigned participant identification reference for this study.

Study data and records will be kept for least 15 years after the study has ended. The re-identifiable/coded (it is possible to use the code to re-identify you) information held by the sponsor, however, will not be destroyed.

By signing this Consent Form you consent to the investigators and the study team members collecting, using and storing your personal information for the purpose of the research project and for any other purposes set out in this Consent Form or otherwise agreed by you

14 What happens if I suffer severe side effects as a result of my participation in this study?

If you suffer any complications as a result of this study, please contact us as soon as possible. In case of an emergency, contact 000.

If, as a result of your participation in this study, you become ill or are injured, immediately advise trial staff. A study clinician will evaluate your condition and then discuss treatment with both you and your regular treating doctor.

In the event of loss or injury, please contact the Chief Principal Investigator or the study team.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

15 What do I do if I need to seek compensation for injury?

If you are injured or experience severe side effects, you can take your complaints or requests for compensation to the Chief Principal Investigator at clinicaltrials@mq.edu.au or please call (02) 9812 2956.

16 What happens when the study ends?

The study team will advise what are your options at the end of the trial. You should continue to see your health practitioner(s) as required for your health.

If there's evidence to support the safety and effectiveness of the study drug, WP001, we will seek to implement an open-label extension stage of the study to allow access to WP001 for participants that received placebo. Currently we cannot foresee as to when we will have results to determine this; once we have the results, the research team will decide whether they wish to proceed with an open-label extension.

If we proceed with the open-label extension stage, we'll contact participants who received the placebo and remained in the study for the entire intervention.

17 Could the researchers stop the study early?

Yes, if it does, the study doctor will let you know and explain the reason behind the decision.

The researchers may stop the study early or the study doctor may stop you from taking part in this study at any time, even if you want to continue, for reasons that include but are not limited to the following:

- Your safety would be at risk if you continued in the study
- You failed to adequately follow instructions or procedures.
- You need a treatment that is not allowed by the study.
- The study has been cancelled.

18 Will the results of the study be published?

A description of this clinical trial will be available on the Australian New Zealand Clinical Trials Registry. This website will not include any information that can identify you. At most the website will include a summary of the results.

Once the study is complete, the researchers will prepare a summary of the results in plain language. Please advise the study team if you'd like to receive a summary and know about the study results. This may be provided to you via an email or a letter.

To protect your privacy, no information will be published that could identify you as a participant in this study. The intention of this study is to gather data however the data will be de-identified. This may take some time and should be discussed with the study doctor.

Woke Pharmaceuticals may request a de-identified copy of any study data.

Deidentified study data may be published in a scientific repository to facilitate open science.

19 Who is conducting and paying for this research?

This is an investigator-initiated study sponsored by Macquarie University and is funded by Woke Pharmaceuticals. Woke Pharmaceuticals is not involved in the study design or how the study is being conducted.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

20 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 clinical trial have been approved by the Macquarie University Human Research Ethics Committee (Medical Sciences).

This project will be carried out according to 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.

21 Who do I contact if I have a question or complaint?

We have included several contacts for you below. Who you contact depends on what information you need:

For all study enquiries or if you want to talk to the study team at any time:

Name	Clinical Trials Staff
Position	Clinical Trials Coordinator or Assistant
Telephone	(02) 9812 2956
Email	clinicaltrials@mq.edu.au

For situations that are after hours please call the Macquarie University Hospital switchboard on (02) 9812 3001 and state the name of Dr Vince Polito or Dr Joanne Shannon and the name and/or number of this trial.

If you experience any side effects or complications as a result of this clinical study, you should contact the study team as soon as possible. They will arrange appropriate medical help.

24-hour medical emergency is available by contacting 000 or going to your nearest hospital.

If you wish to discuss the study with someone not directly involved, particularly about policies, information or complaints about the conduct of the study or your rights as a participant, you may contact any of the following contacts:

Complaints contact person

Name	Macquarie University Research Office
Position	Director, Research Ethics and Integrity
Telephone	(02) 9850 7854
Email	ethics@mq.edu.au

Reviewing Local HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Macquarie University Human Research Ethics Committee (Medical Sciences)
HREC Executive Officer	Ethics Secretariat
Telephone	(02) 9850 4194
Email	ethics.secretariat@mq.edu.au

Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

22 The consent form

Sign the consent form only after you have made up your mind to take part in this clinical study. If you wish, we will arrange for someone to read the form to you in a language you understand. You must be provided with a signed and dated copy of the participant information and consent form for your personal record.

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E: clinicaltrials@mq.edu.au

Consent form

Title	A Double-Blind Randomised Controlled Trial of Microdosing with Psilocybin to treat Moderate Depression	
Protocol number	MICRODEP-01	
Project sponsor	Macquarie University	
Chief Principal Investigator	Dr Vince Polito	
Study Doctors	Associate Professor Jonathan Brett	Dr Joanne Shannon
General contact person	Clinical Trials Unit	(02) 9812 2956

Note: All parties signing the consent section must date their own signature.

Declaration by participant

I have read, or have had read to me, and I understand the participant information and consent form.

I have had the opportunity to discuss this with an independent person.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this clinical study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand the purposes, procedures and risks of the research described in the information sheet.

I give permission for my doctors, other health professionals, hospitals, laboratories or ambulances outside this hospital to release information to Macquarie University concerning my medical history, disease and treatment for the purposes of this study. I understand that such information will remain confidential.

By signing this consent form, I give permission for the study Investigator to obtain information from the following for the duration of the study period:

- ambulance transportation
- any admission to any hospital
- Emergency Department visits
- stays in an observation unit
- information from my local doctor

The information collected from these places/persons will only be requested if it is required for this study and will only be used for the purpose of this study.

I consent to my treating doctor/s being notified of my participation in this study and any clinically relevant information noted by the study doctor in the conduct of the study.

I understand that I will be given a signed copy of this document to keep.

I consent to the collection, storage and use of my data and blood samples, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project and
- Unspecified future research

Additionally, you may optionally consent to the following by ticking the appropriate boxes:

☐ I agree to be contacted by study investigators to inform me of new microdosing research opportunities.

☐ I am willing to receive invitations from the study investigators to speak to science journalists about this clinical trial. Agreeing to this does not obligate you to speak to journalists about your experience, it just means we may send you an invitation to do so.

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Signature _____ Date_____

Name of participant (please print) _____

Declaration by study doctor/senior researcher†

I have given a verbal explanation of the clinical study, its procedures and risks and I believe that the participant has understood that explanation.

Signature _____ Date_____

Name of study doctor/researcher† (please print) _____

† A senior member of the study team must provide the explanation of, and information concerning, the clinical study.

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Withdrawal form

Title	A Double-Blind Randomised Controlled Trial of Microdosing with Psilocybin to treat Moderate Depression	
Protocol number	MICRODEP-01	
Project sponsor	Macquarie University	
Study doctor	Dr Vince Polito	
Study Doctors	Associate Professor Jonathan Brett	Dr Joanne Shannon
Clinical contact person	Clinical Trials Unit	(02) 9812 2956

Note: All parties signing the consent section must date their own signature.

Declaration by participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Macquarie University.

Participant to choose 1 of the following options and to indicate which sub-options preferred	
☐ **Option 1: Withdrawal from Study Treatment Only**	I wish to discontinue study treatment only but continue study procedures/assessments via: ☐ Follow-up visits and procedures ☐ Telephone, email, and/or clinic visits
☐ **Option 2: Withdrawal from Study Treatment and Follow-Up**	I withdraw consent from all future participation in this study. ☐ You may contact me or my family physician to determine my health status only and to provide continuous follow-up of associated clinical outcome information. ☐ You MAY NOT contact me or my family physician at study closure to determine my health status.
Please choose 1 of the 2 options below to indicate what happens to samples previously collected from you, when you withdraw from study participation. ☐ The sponsor may retain samples previously collected from me. **OR** ☐ I wish for my previously-collected samples to be destroyed.	

Signature _____ Date_____

Name of participant (please print) _____

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MACQUARIE University
SYDNEY·AUSTRALIA

Declaration by study doctor/senior researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Signature _____ Date_____

Name of study doctor/researcher† (please print) _____

† A senior member of the study team must provide the explanation of, and information concerning withdrawal from, the clinical study.

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.