Monash University Human Ethics Research Committee
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Study Explanatory Statement

Psilocybin assisted therapy for opioid use disorder (Path-OUD)

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Study Location
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Study email: Path-OUD@monash.edu

You are invited to participate in the screening stage of this study. Please read this Information Sheet in full before deciding whether or not to participate in this research.

IMPORTANT: If you are eligible for this study, it will be necessary to attend all study appointments. If you would like further information about any aspect of this project, please contact the researchers via the phone number(s) or email address(es) listed above.

Purpose of the Study

This study is investigating whether a single supervised dose of **psilocybin**, a psychedelic compound found in some mushrooms, offered as part of **Psychedelic-Assisted Therapy**, can help reduce opioid use and improve wellbeing in people who are receiving treatment for opioid use disorder (OUD). Psilocybin has shown promise in earlier studies as a tool to support therapy and enhance wellbeing and cognitive function.

We aim to understand whether psilocybin can help reduce cravings, support long-term recovery, and improve thinking abilities like flexibility, focus, and decision-making. We also want to learn how psilocybin affects the brain and whether certain brain or thinking patterns can help predict who may benefit most from this type of therapy.

This research is part of a growing effort to explore new treatment options for people living with opioid addiction. It will also help us understand how psilocybin affects the brain and behaviour, with the goal of improving support for people in recovery.

Why Was I Chosen for this Research?

You were invited to take part in this study because of your experience of opioid use and are currently stabilised on a medication-assisted treatment of opioid dependence (MATOD) program, such as buprenorphine or methadone. The study is seeking people who have an opioid dependence and use non-prescribed opioids (such as heroin or non-prescribed pharmaceutical opioids such as morphine, oxycodone and codeine) on top of their MATOD medication, and who may benefit from additional psychological support to help reduce opioid cravings and improve long-term wellbeing.

We are interested in learning how Psilocybin-Assisted Therapy might support people like you who are already on a stable treatment plan and are looking for ways to strengthen their recovery, improve decision-making, and build a more flexible and goal-directed mindset.

Who Cannot Take Part in This Study?

To protect your safety, you **cannot take part** in this study if any of the following apply to you. These are known as **exclusion criteria**.

You cannot take part if you:

- You are **under 18 or over 60 years old**
- You are currently enrolled in **another clinical trial** or have received an investigational drug in the past 30 days
- You are unable to attend the **study visits** or **follow instructions** related to safety during the study.

- You are **claustrophobic** or uncomfortable lying still in enclosed spaces
- You have any **metal objects** in your body that could interfere with MRI:
    - Pacemakers, metal implants, surgical clips, shrapnel, or broken needles
    - Permanent retainers or other dental work (case-by-case basis)
- You have any **non-removable medical patches**
- You have ever been diagnosed with:
    - Schizophrenia or any other psychotic disorder
    - Bipolar disorder
    - Hallucinogen-persisting perception disorder (HPPD).
- You have a **first-degree relative** (parent, sibling, or child) with schizophrenia or another psychotic disorder, or bipolar disorder.
- You currently have **severe major depression** (mild or moderate is okay if stable and not on medications that can interact with psilocybin to increase risk to participation).
- You experience **active thoughts of suicide or self-harm** or **attempted suicide** in the recent past.
- You have any **mental health condition** that in the opinion of the study team, could place you at risk
- You have a **moderate to severe substance use disorder** for any substance **other than** opioids, alcohol, cannabis, or nicotine
- You have used **psychedelics in the past 6 months**, or have used them **more than 50 times in your life.**
- You are currently pregnant, planning pregnancy or breastfeeding
- You have a **BMI of less than 17**
- You have a history of:
    - **Seizures or epilepsy**
    - **Serious head injury**, including loss of consciousness for more than 3 minutes
    - **Stroke** or neurological conditions that may interfere with MRI
- You have significant issues with:
    - **Liver, kidney, lung, heart, or endocrine function (diabetes, thyroid)**
    - **HIV**, or other immune-related conditions
    - **Diabetes**, **Crohn's disease**, or any condition your doctor believes makes participation unsafe
- You've ever had a diagnosis of **heart problems**, including:

    - Coronary artery disease, arrhythmia, long QT syndrome
    - Congestive heart failure or heart attack
    - Artificial heart valves
- Your **blood pressure is too high** as assessed by the study doctor:
- You are allergic to **gelatine or lactose**, which are used in the capsule
- You currently take medications or drug types which can't be paused or managed safely including:
    - Herbal supplements with serotonergic activity, such as **St John's Wort**
    - Drugs that interact with psilocybin metabolism, including:
        - Rifampicin, carbamazepine, phenytoin, efavirenz, nevirapine
        - HIV protease inhibitors, ketoconazole, erythromycin, clarithromycin
        - Fentanyl, pimozide, midazolam, triazolam, ergot alkaloids, simvastatin, lovastatin
    - **antipsychotics**, or other **psychoactive medications**.

If you are taking **antidepressants such as SSRIs** these are assessed by the study team or doctor on a case by case to determine if you are eligible to take part.

Cautions and Special Cases

Even if you meet most criteria, there are some situations that may still make you ineligible. These will be discussed during screening with the study doctor – some cases might be:

- **Borderline blood pressure or heart function** that may require extra testing
- Use of medications not on the excluded list but may interfere with psilocybin's effects
- Any condition (medical or psychological) that the study doctor feels could make participation unsafe or inappropriate.

If you're unsure whether any of these apply to you, we encourage you to speak with our team. A full screening will be conducted before any participation, and all decisions are made to ensure your safety and wellbeing.

What Does the Research Involve?

If you choose to take part in this study, your involvement will last about **6-7 months**, with the majority of visits happening in the first **4-5 weeks**. You will be randomly assigned to

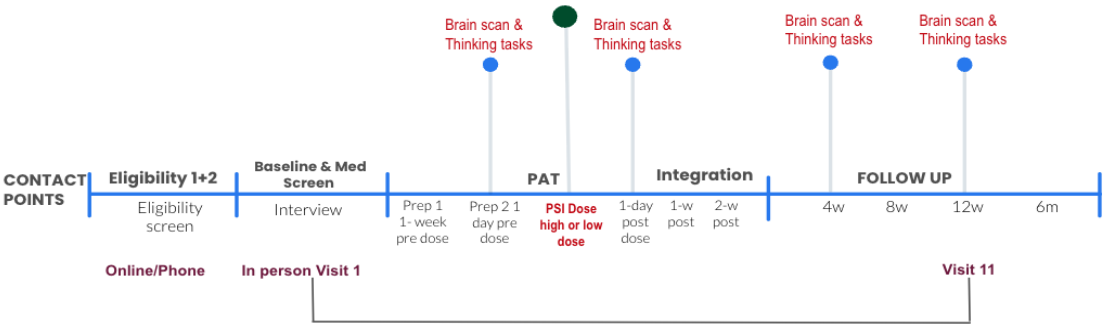
receive either a high dose (66% chance) or low dose (33% chance) of **psilocybin**. You will not know which dose you receive, and neither will the researchers and psychologists directly working with you, to ensure the study results are fair and unbiased.

Regardless of which dose you receive, all participants will receive the same level of care, including therapy and medical support throughout the study. Transportation costs to and from the research centre will be provided.

You will be asked to provide your consent for the study team to contact your regular general practitioner (GP) and/or MATOD prescriber as well as your MATOD dosing pharmacy. We are required to contact your GP and/or MATOD prescriber to inform them that you are engaged in an additional treatment for Opioid Use Disorder and to obtain information about your medical history and MATOD use. Your MATOD prescriber needs to know about any other treatments you're using, to better assess the safety of the pharmacotherapy medication they prescribe for you. As this is a study requirement, if you decide not to consent, you will be ineligible for this study.

Please read on for a more detailed description of the study requirements. A diagram and a table summarising the study requirements is also provided.

Timeline of Path-OUD Study Appointments



Summary of Path-OUD study appointments including Time Commitments

In-person Visits		Estimated Time
Week 1		
Visit 1	Medical Screening and Assessments	~ 5 hours
Week 2		
Visit 2	1st Preparation Session and Baseline data collection	~ 3 hours
Intervention Week (Week 3)		
Visit 3	2nd Preparation Session and Baseline data collection	~ 5 hours
Visit 4	*Intervention Session- Psychedelic Dosing Day*	Full day
Visit 5	1st Integration Session	Half day
1 week after dosing		
Visit 6	2nd Integration Session	~ 3 hours
2 weeks after dosing		
Visit 7	3rd Integration Session	~ 3 hours
4 weeks after dosing		
Visit 8	1st follow-up assessment	Full day
8 weeks after dosing		
Visit 9	2nd follow-up assessment	~ 3 hours
12 weeks after dosing		
Visit 10	3rd follow-up assessment	Full day
6 months after dosing		
Visit 11	4th follow-up assessment	Half day

Please note, the times above are an estimation based on previous experience, and your time may vary.

Screening and Eligibility Interviews (~ 4 hours in total)

You'll first complete an online screening questionnaire (20-30 mins), a zoom or phone interview (around 1-1½ hours) and an in-person medical screen (around 2 hours)to see if you are eligible and if this study is right for you. This includes talking about your medical history, mental health, and substance use, along with some medical checks and a blood test.
We will ask for your consent at each stage of the screening process. During the Zoom or phone interview, we will record and document your verbal consent, and during the in-person medical screening, we will document your written formal consent.

Preparation Sessions (2 x 2-hour sessions)

If eligible, you'll attend **two therapy sessions** with a trained psychologist . These sessions help you build trust with the team, feel prepared, and set a personal intention for your psilocybin session.

Baseline Measurement Surveys and questionnaires (4-5 hours in total over two visits)

As we are a scientific study, we need to measure any change in your non-prescribed opioid use, mental health and wellbeing and cognitive ability. You will therefore complete a series of questionnaires or surveys which measure these domains in the week ***before the dosing session***, and again in the ***period after the dosing session*** (follow-up).

Pre-Dose Brain Imaging and Thinking Tasks (2.5–3 hour session)

You'll visit Monash Biomedical Imaging, for a **MRI scan** and complete some computer-based tasks that assess memory, attention, and decision-making. These will be carried out on ***the day prior to your psilocybin dosing session***.

Dosing Session (6-8 hours on one day)

You'll take a **single capsule of psilocybin** (high or low dose) in a safe and supportive clinical environment. You'll be monitored by trained staff the entire time. A doctor will be readily available. After the session, you'll be supported in returning to a safe place.

Integration Sessions (2-3 x 1½-2 hour sessions)

These sessions happen on the day after and immediate weeks after your psilocybin experience. They are a chance to talk through the experience and find ways to apply any insights to your life and recovery.

Post-Dose Brain Imaging and Thinking Tasks (2.5–3 hours per session)

You'll repeat the same MRI scan and computer tasks to see how your brain and thinking may have changed. The first will be carried out ***the day after your psilocybin dosing session***, and again at ***4 weeks*** and at ***12 weeks*** after the psilocybin dosing session.

Follow-Up (4 visits over 6 months)

You'll be invited back to complete ***2-hour interviews*** at ***4 weeks, 8 weeks, 12 weeks, and 6 month*s** after your psilocybin session to repeat the baseline measurement surveys and questionaries. This allows us to track longer-term changes in your wellbeing and your use of non-prescribed opioids.

As mentioned previously, you will also repeat the MRI scan and computer tasks at the *4- week and 12- week post psilocybin session visits* to see how your brain and thinking may have changed. Please note that these visits will therefore be longer – around 4-5 hours

All assessments are done by qualified staff and will involve a mix of interviews, surveys, brain imaging, and computer tasks. Some visits also include medical checks (e.g., heart rate, blood pressure, or blood tests).

Support persons may be allowed to attend certain sessions, but due to safety protocols, they may not be present during medical or dosing procedures.

Important Note: We will also ask to collect and securely store your de-identified data (meaning your name and any identifying information is removed so you cannot be identified). This includes survey responses, MRI scans, and other assessments. Your personal information will always be kept private and separate from the study data.

Clinical Tests and Biospecimens

In this study, you will also be asked to consent to biospecimen testing. If you participate in the study, the following samples will be collected from you:

- **Hair Sample:** We take a very small amount of your hair at the Baseline Measurement appointment and again at the Follow-Up appointments. This allows us to assess for quantitative confirmation of opiates. We will only test for opioids with this sample.
- **A Pregnancy test (only where applicable):** will be conducted to confirm you are not pregnant. These may occur during screening and at dosing to ensure your safety.
- **Urine Drug Screen (UDS);** You will be asked to complete a UDS during the screening visit, on the dosing day, and at your follow-up visits. Before dosing, the UDS will provide information about your medication use and help confirm your safety. At the other

timepoints, the UDS provides important information to the study doctors about your non-prescribed opioid use and your MATOD use.

- **Blood collection:** You will be asked to attend a pathology centre before your in-person screening interview in order to provide a small sample of blood. This will allow us to check routine health markers (e.g., full blood count; kidney and liver function), as required and help assess if the study is right for you. The study team will discuss this with you at the screening stages of the study. We may take a further blood sample during the study period – we will advise you of this ahead of time.

What are the Benefits of Participating in this Study?

The effectiveness of Psilocybin in assisting people who are living with Opioid Use Disorder has not yet been established –our study is the first to look at this in Australia. Participants may benefit from the therapy provided as part of the *Psychedelic-Assisted Treatment* process. Please remember, this study isn't a treatment for acute withdrawal, nor is it intended to provide immediate symptom relief. It is being explored as a support to ongoing treatment that may support long-term recovery and is *not* a replacement for medication-assisted treatment or counselling. During this study, you should not replace or stop your existing treatment medication without consulting a doctor.

What are the Risks of Participating?

Risks During Screening and Assessments

Some questionnaires and interviews in this study involve sensitive topics - such as mental health, trauma, and substance use - which may cause emotional discomfort, upset, or distress. This usually subsides but if you continue to feel distressed any of the following may happen to support you: A **risk assessment** may be conducted to understand how you're feeling and whether you need extra support

- A **psychologist or mental health clinician** on our team will review any assessments and provide **feedback and support via phone.**
- If there is a risk of self-harm or suicide, a **safety plan** will be developed with you.
- A **Crisis Assessment and Treatment Team (CATT)** may be contacted.

- We may refer you to **Monash Medical Centre** (03 9594 6666), or a nearby mental health service.

- Where appropriate, we may refer you to the **Turner Clinics**, which offer **subsidised mental health care**. If you need support during or after the study, a list of trusted **support and crisis services** that are free and confidential are provided below.

Counselling and support services

- **Lifeline (24/7):** 13 11 14 — crisis support and suicide prevention. Text 0477 13 11 14; webchat available.
- **Beyond Blue (24/7):** 1300 22 4636 — mental health counselling and referral.
- **13YARN (24/7):** 13 92 76 — confidential crisis support for Aboriginal and Torres Strait Islander peoples.
- **Directline (24/7)** 1800 888 236 — confidential phone or online alcohol and drug counselling and referral for people in Victoria.

Call 000 if life is in danger.

Risks Associated with taking Psilocybin

Psilocybin is a psychoactive substance that can affect thinking, perception, and emotions. In Australia, psilocybin is classified as a "Schedule 9 controlled substance", meaning it is prohibited for general use and can only be used for approved conditions, in approved medical or research settings. In this study, psilocybin is administered legally under a Schedule 9 licence, with strict medical supervision and approval from the Victorian Department of Health and the Therapeutic Goods Administration (TGA).

Psilocybin can cause a range of **psychological and physical effects**, that *typically* begin within 30–60 minutes, peak around 2 hours, and last **approximately 4 to 6 hours**. The effects are **unpredictable and vary greatly** between individuals, even with the same dose. You may experience:

- **Changes in thought processes**, such as faster or slower thinking
- **Visual and sensory changes**, including colour intensification or pattern perception
- **Altered time perception**, with time feeling slower or faster than usual

- **Depersonalisation or dissociation**, feeling detached from yourself or surroundings
- **Emotional shifts**, including joy, sadness, fear, awe, or a sense of connection
- **Reduced concentration or impulse control**, including disinhibited emotional expression such as laughing or crying
- **Unusual bodily sensations**, tingling, lightness, tension release, yawning, or fatigue

While psilocybin is not physically toxic and does not cause compulsive drug-seeking, it can temporarily increase vulnerability to distress, especially if you feel unprepared or anxious. The most common psychological risks include:

- **Anxiety or panic**
- **Paranoia or fear**
- **Emotional discomfort or confusion**
- **Temporary disorientation or loss of awareness that you are in a research setting**

These reactions are often referred to as a "bad trip." They are usually **temporary and manageable**, particularly in the safe and supportive setting used in this study. You'll be continuously monitored during the session by trained clinical staff who follow a detailed support plan. A doctor is on call. If you feel distressed during the session, staff will offer:

- **Reassurance and calming strategies**
- Access to **a quiet recovery space**
- In rare cases, **anti-anxiety medication** may be prescribed by the study doctor

A **follow-up** will take place the next day as part of the Integration session to check in on your wellbeing and provide support if needed.

Although extremely rare, there is a **small risk of long-lasting psychological effects,** especially for people with a personal or family history of psychotic-spectrum disorders. These may include:

- **Prolonged psychosis**
- **Hallucinogen Persisting Perception Disorder (HPPD)** – a rare condition where perceptual disturbances (e.g., trails, halos) may recur after the drug wears off. The

risk of HPPD after psilocybin administered in controlled settings is very low (Leistenschneider et al., 2024).

To reduce this risk, the study includes thorough **psychiatric screening** and excludes people with:

- Diagnosed psychotic or bipolar disorders
- A first-degree relative with schizophrenia or related conditions
- Certain psychiatric conditions that are not suitable for this study.

Physical side effects of psilocybin may include:

- **Increased heart rate or blood pressure**
- **Nausea or vomiting**
- **Headache**
- **Muscle tension or fatigue**
- **Dilated pupils or light sensitivity**

You will be medically assessed before and after dosing to ensure it is safe for you to participate. Emergency procedures are in place if needed.

Psilocybin may interact with other medications.
You must inform the research team about all prescription and non-prescription drugs you are taking. Certain drugs and medications, including antidepressants, SSRIs, antipsychotics, mood stabilisers, and some herbal supplements (e.g., St John's Wort), may **interfere with psilocybin's effects** or **increase the risk of adverse reactions**. If these cannot be safely paused or managed before the dose, you may not be eligible for participation. The study team or doctor will help you work out if the medications and drugs you are currently taking, make it suitable for you to participate in this study.

What happens after the session?
Most people feel physically and mentally back to normal by the next day. However, psilocybin may leave **temporary emotional or cognitive after-effects**, such as fatigue, reflection, or feeling unsettled. An increase or decrease in focus and transient headaches in the period after the psilocybin session are also common. You are encouraged to avoid major

life decisions, intense social situations, or physically demanding activities for 24 hours following your session.

Important: You must not drive or operate machinery for at least 24 hours after your dose.

Will psilocybin show up on drug tests?

Psilocybin is not commonly tested for in standard drug screens, but:

- **Urine and blood tests** may detect it for up to **24 hours**
- **Hair tests** may detect it for up to **90 days**

These times vary depending on your metabolism, weight, and other personal factors. Please notify your treating team or workplace if drug testing is a concern.

Important safety note

This study is **not a substitute for standard medical care**. Psilocybin is used in this study to explore its potential to enhance psychological wellbeing after participants are already stabilised on medication-assisted treatment (e.g., Suboxone or methadone). It is not designed to relieve acute withdrawal symptoms or replace any part of your existing treatment plan.

Risks Associated with MRI Scans

MRI (Magnetic Resonance Imaging) is widely used and considered **very safe**. It uses magnetic fields and radio waves—not radiation—to create detailed images of the brain.

While there are no known long-term risks, some people may experience:

- **Claustrophobia** – feeling anxious or confined in the scanner
- **Loud noises** – the scanner makes knocking or buzzing sounds
- **Tingling or warmth** – harmless effects from magnetic fields

To make the scan more comfortable:

- You will wear **earplugs or headphones**
- You will be given a **call button** to stop the scan at any time
- You can **withdraw from the scan** if you feel uncomfortable

Before the scan, you'll complete a **safety checklist** to make sure you don't have any metal in your body (such as implants, surgical clips, or shrapnel) that could pose a risk.

In rare cases (~2%), MRI scans may show something unexpected in the brain. These are called **incidental findings**. If this happens:

1. You'll be told during screening that it's a possibility.
2. You'll be asked to nominate a **GP** who could receive the results.
3. If something is found, the scan will be reviewed by a radiologist and, if needed, sent to your GP.
4. You will be asked to make an appointment with your GP to discuss any incidental findings.

These policies follow **Monash Biomedical Imaging** procedures and are designed to support your care. Before any procedures, we will obtain your written consent confirming you have read the Explanatory Statement, nominating your GP/GP clinic, indicating whether we may advise your GP if an incidental MRI finding requires clinical follow-up, and indicating whether the Chief Investigators may be notified if such a finding is identified.

What is the Cost Associated with Participating?

You will not be expected to pay for any of the tests being conducted. The blood tests you will be asked to complete before attending the in-person Medical Screening appointment will be paid for by the study. The cost of transportation to Monash Biomedical Imaging for study assessments will be covered with Cabcharge vouchers.

Reimbursement Information

You will be reimbursed for your time and involvement in the study. Total compensation may be up to $1,520 AUD, provided in increments across multiple visits. Reimbursement is provided in the form of gift cards for each completed component of the study. A detailed reimbursement schedule will be provided after eligibility screening.

Who is Funding the Study?

This study is funded by the Wellcome Leap Untangling Addiction Program and sponsored by Monash University.

What will happen to the information collected about me? Will it remain private?

We take your privacy seriously. All information you provide is kept **confidential and secure**.

- You'll be assigned a **code number**, and your name is kept separate from your data.
- Personal information (like your name and contact details) will be stored on **password-protected computers** and in locked filing cabinets at Monash University.
- Only the authorised research team will have access to your identifying information.
- Your data (e.g., brain scans, questionnaire responses, clinical and biospecimen test results) will be stored securely and may be used for future research, but only in **de-identified form**, meaning no one can link the data back to you.
- Identifying information will be **destroyed after 5 years**, in line with legal requirements.
- Some de-identified data may be uploaded to public scientific databases as part of **Open Science practices**, to help other researchers and meet journal requirements. These shared datasets will not include personal information and cannot identify you.
- **Please note**, your **personal details may also need to be made available to Monash finance**, if requested for audit purposes.
- **Your biospecimen samples**: Your hair samples are used only to confirm reports about your non-prescribed opioid use. Your blood samples are used for clinical safety in this study (screening, and dosing). As with all study results, the results of these biospecimen tests are de-identified when the study findings are published and for the purposes of data sharing in future research. Your biospecimen samples are not used for genetic testing, or biobanked. However as part of planning for future related studies, you will be asked to consent to the storage and future use of your biospecimen samples for the purposes of future studies.
    - ***Storage and disposal:*** Samples are processed by accredited pathology services and disposed of under standard policy. Tell us if you have cultural or personal preferences—we will accommodate reasonable requests when feasible.
    - ***Clinically important results (incidental findings):*** If a biospecimen test result suggests a health issue, a study clinician/doctor will discuss this with you and

advise follow-up. Because these tests are essential for safety, you cannot opt out of being told important results.

- **Right to withdraw:** You may withdraw at any time. Results already generated remain in the study's safety record. Samples that have already been processed or disposed of cannot be retrieved.

If you are recruited through TrialFacts, your screening data will be securely stored in the cloud and accessed only by approved recruitment and study personnel.

- TrialFacts will **keep the screening data indefinitely** and use it for future recruitment services. In practice, this means they may contact you if you are eligible for involvement in another study in the future, to ask if you are interested.

If you have any questions about our data storage policy and processes, please do not hesitate to contact us at Path-OUD@monash.edu

Do I Have to Take Part in the Study?

Participation in any research study is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time. Deciding not to take part, or withdrawing after the study has begun, will not affect your current or future clinical care or entitlements with your usual treating team (e.g., medication-assisted treatment, GP, counselling), Monash University services, or your relationship with the study team. Before you make your decision, you can ask one of the researchers any questions you have about the study. It is important that you sign the consent form only after you are satisfied with the answers.

What are My Alternatives if I Decide Not to Participate?

You do not have to participate in this study if you do not want to. You can withdraw your consent at any time, and request that all data be destroyed. Choosing not to participate—or withdrawing after participation has begun—will not affect your access to services to which you are entitled, and non-participation will not affect your ability to participate in future research. If you revoke consent to participate while you are under the acute effects of psilocybin, you will be required to remain onsite under the care of the research team until the effects of psilocybin have reliably ended, approximately 7 hours after administration. This is

to ensure your safety and that you are discharged only when the effects of the study drug have worn off. The study doctors will make an assessment of your mental state and ability to be safely discharged from the study site.

Who Can I Contact for Information About the Study or Results?

If you require further information about this project or have any concerns or feedback, please contact us at Path-OUD@monash.edu. You can also contact the Chief Investigator, A/Prof Adeel Razi (Ph: (03) 9905 0109 or adeel.razi@monash.edu).

Who Can I Contact if I Have a Complaint?

If you have any complaints about any aspect of the study, the way it is being conducted or any questions about your rights as a participant, contact Monash University Human Ethics Research Committee:

Monash University Human Research Ethics Committee
Executive Officer
Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111
Research Office
Monash University VIC 3800

Tel: 03 9905 2052
Email: muhrec@monash.edu