

Participant Information Sheet

People Who Drive Under the Influence of Prescription Medication

NOTE: This Participant Information Sheet will remain with the University of Queensland and University of Tasmania research teams for their records.

Project Title: Drugged-Driving Effects on Driving Performance

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Ethics Approval Numbers – UQ: 2025/HE000945; UTAS: 2025/H40445

You are invited to take part in a study exploring how the use of drugs or combinations of drugs, medications or alcohol (poly-drug use) affects a person's ability to drive safely. Please read the following information about the project to decide whether you want to participate in this research. Please feel free to ask any questions about our involvement in the project.

If you decide to participate in this research, please remember that participation is voluntary. If you do not wish to participate, you do not have to. If you decide to take part and later change your mind, you are free to stop at any time, and you do not need to give any explanation for your decision to stop participating. If you stop participating and indicate it in the Consent Form, your data will not be used in the research.

You will be given a Consent Form to sign, and you will be given a copy to keep. Your decision whether you take part, or not to take part, or to take part and then withdraw, will not affect your relationship with the University of Queensland.

Please note that your identity and the data collected from this study will be confidential. This Participant Information Sheet describes what is involved in the study, and you should read it in full before deciding whether to participate. Please keep this information sheet as a record.

What is this research about?

A research team, led by Dr Shamsi Shekari, at the School of Psychology, the University of Queensland, are conducting this study. We are interested in understanding how habitual behaviours, such as sleep, drug or alcohol use or taking prescription medications, might affect people's ability to focus, react quickly, or complete driving-related tasks. We are not testing your driving ability, judging your driving ability, or making any medical diagnoses. The findings will help improve safety-related knowledge and support future public health and road safety initiatives.

The University of Queensland and the University of Tasmania Human Research Ethics Committee have approved the study (UQ: 2025/HE000945, UTAS: 2025/H40445).

Am I eligible?

To take part in this experimental study, you must:

- Must live in either Brisbane or Hobart.
- Be between 18 and 65 years of age.
- Regularly sleep more than 6 hours per night.
- Hold a valid driver's licence (provisional or open).
- Be willing to provide an oral fluid (saliva) and breath sample to screen for the presence of drugs and alcohol.
- Do not use any illicit drugs.
- Be prescribed at least one medication that contains a substance that affects safe driving , including
 - Stimulants (dexamphetamine, lisdexamfetamine, or methylphenidate),
 - Opioid medications (morphine, oxycodone, hydromorphone, fentanyl, methadone, or buprenorphine),
 - Benzodiazepines or (diazepam, alprazolam, lorazepam, zolpidem, or zopiclone, Temazepam, Valium, or Xanax) or Seroquel/quetiapine
 - Hallucinogens or dissociatives (ketamine, esketamine, psilocybin, or MDMA)
- Be willing to provide proof of prescription.
- Have normal vision (either with or without prescription glasses or contact lenses).

If you experience any unanticipated changes in life circumstances that may affect your ability to engage in the experimental study, please notify the research team as soon as possible to discuss your ability to continue the study.

What will I need to do?

After you pressed the “Participate in the Medications group” button on the study website, you will be directed to a screening page where you are asked to provide your consent to participate in the screening process. If you are deemed ineligible, the screening page will ask for your permission to make future contacts for upcoming related projects. If you meet the criteria for participation, the researcher will schedule an in-person one-hour induction session for you at the School of Psychology, UQ, St Lucia. At the induction session, the researcher will explain the study in detail, provide you with a link to review the Participant Information Sheet and answer your questions. The researcher will then obtain your verbal consent and ask you to complete some computerised questionnaires about your general health and sleep quality. You can choose not to respond to the questions if you feel uncomfortable. At the end of the induction session, you will be given an actiwatch (a wrist watch activity monitor) to wear continuously for three nights to monitor your recent sleep-wake pattern. You will also be emailed a short sleep diary every morning for at least three days before your laboratory session to monitor your recent sleep patterns in preparation for your lab visit. You will be required to attend a 1.5-hour simulated driving laboratory visit at the University of Queensland. You will be asked to abstain from caffeine-containing products for 8 hours before the test session, and from illicit drugs for the duration of the study. You will also be asked to consume your prescription medication as usual.

Before the start of the lab session, you will be asked to sign a written consent form. During the lab session, you will begin with completing short questionnaires about your recent drug use, alcohol consumption, and a brief breath alcohol test to record any potential alcohol levels in your system. You will then provide saliva samples to screen for the presence of drugs using validated testing devices. In case of successful screening, the research team will collect the actiwatch you have worn for the past three nights and download your sleep data.

The core part of your session will involve a series of computerised tasks designed to assess your attention, reaction time, and cognitive functioning. These tasks are commonly used in research to understand how substances affect the brain’s ability to process information. You will also complete a traffic conflict test that simulates driving conditions, and afterwards, rate how well you believe you performed. Following these tests, you will undertake a driving simulation using a desktop-based system that mimics real-life driving scenarios to evaluate your driving performance under different drug conditions. You will undergo postural and balance tests at the end of the session. Please note that we are not judging your performance on the driving simulator, the traffic conflict test, or postural and balance tests.

As a thank you for your time and contribution, you will be reimbursed with a \$200 Gift Pay for your time and for providing sleep data and specimen samples.

Source of funding

Department of Infrastructure, Transport, Regional Development, Communications and the Arts funds this project.

What type of consent should I give?

You will provide your consent at two stages: during the induction session, you will be asked to give verbal consent to ensure that you fully understand the study before your test session is scheduled. Then, during your test session, you will be asked to sign a written, extended consent form to participate in the research. When you agree to extended consent, your data can be reused in future projects that are an extension of this project, closely related to this project, or in the same general area of this research. Your consent form will include permission to collect biospecimens (saliva and breath samples) and fill out a brief sleep diary before each test session.

As part of the consent, if you do not permit future contacts, we will remove your personal information after the completion of the study to protect you from future contacts. Also, if you tick the relevant box in the Consent Form, we will remove your data from the dataset if you withdraw from the study. However, you can remove your data before the conclusion of the research project, as all personal identifiers will be deleted upon completion.

What are the possible benefits of taking part?

While there may be no direct personal benefit from participating in this research, your involvement is highly valuable and may offer some indirect advantages. By participating in this study, you provide data on driving under the influence of prescription medications. Your data will be compared with other groups of participants to understand how poly-drug use affects driving ability, attention, and reaction time. This knowledge can help shape future road safety policies, support more effective drug-driving enforcement strategies, and ultimately contribute to reducing crashes and saving lives on Australian roads.

For the broader community and research field, this study will provide critical evidence about the impairing effects of drugs and poly-drug use on driving performance. The findings may help establish more scientifically valid approaches to detecting drug-impaired driving and support the development of safer, evidence-informed road safety laws and technologies.

What are the possible risks and disadvantages of taking part?

Taking part in this study is voluntary, and while most people participate without any issues, there are a few possible risks you should know about. We have explained each one below and what we'll do to minimise them.

Psychological Discomfort from Task Performance or completing the questionnaires: During the study, you will complete tasks such as reaction time and hazard perception assessments. You may feel that your performance is not as good as expected and might feel self-conscious, embarrassed, or discouraged, particularly if you compare your results to others or believe you have “failed” a task. To help with this, we will clearly explain (in both the written information and verbal instructions) that the tasks are not diagnostic, and errors are completely normal and expected. You can stop or skip any part of the study if you feel uncomfortable, with no penalty. After your session, you will be offered a friendly and supportive debrief and a list of support services if you want to talk to someone afterwards, such as Lifeline (13 11 14), the Alcohol and Drug Information Service (1800 250 015) and local services available at The University of Queensland, such as Student Counselling Services, Crisis Line, and Self-Help Resources.

Risk of motion sickness: The study includes a 25–30-minute driving simulation. The simulator is designed to minimise visual strain and discomfort. If you are prone to motion sickness, you might feel dizzy, nauseous, or disoriented. We will ask if you have had motion sickness before to reduce this risk. You can take breaks or stop the task anytime if you feel unwell. Also, water, fresh air, and short rests will be available throughout.

Risk of minor discomfort or inconvenience: Each session lasts 1.5 hours. There may be minor fatigue from completing computer-based tasks and concentration-heavy tasks. You can take breaks between tasks and skip anything you do not want to do.

All participation is voluntary. You can take breaks, skip any part of the session, or withdraw from the study anytime. Your safety is a priority, and the research team is committed to providing a safe and supportive environment throughout your participation.

What will happen to the information about me?

The study follows strict privacy, confidentiality, and ethical standards to ensure your information is handled responsibly and kept safe at every stage. All information collected about you will remain confidential.

When you participate, we will collect information such as your questionnaire responses, results from driving and cognitive tasks, and biological samples (like breath or saliva). This information will be stored securely and handled according to national ethical guidelines and university policies. Any biological samples collected (saliva and breath) will be labelled only with your study code and destroyed after they are analysed, following biosafety procedures. Your research data will be stored securely at the University of Queensland while conducting and following the study's conclusion.

During the study, we will assign you a unique study code to protect your identity; This code will be used on all your data and samples instead of your name. Your name and contact details will be stored separately from your study data in an encrypted file. These details are used only during the study to contact you about session times. All electronic data will be saved on password-protected university servers, and paper records will be stored in locked cabinets or archived securely. Only researchers who are listed on the approved ethics protocol will be able to access the data.

If you consent to future contacts, your personal information will be stored for 5 years in a password-protected file, separately from your participant code. Otherwise, all identifying information, such as your name, contact details, and the document that links your name to your study code, will be deleted to ensure your identity's confidentiality and protect you from unwanted contacts in the future. Additionally, at the end of the study, data from paper records will be scanned and saved digitally; then the paper records will be shredded. We also allow you to update your responses before your data is analysed.

Your data will be reused in future projects that are an extension of this project, closely related to this project, or in the same general area of this research. At the University of Queensland, your Consent Form will be stored securely for 15 years, and other raw data collected from you (deidentified data) will be stored for five years after the study is published. After these periods, all records will be permanently destroyed using secure methods. The metadata (research findings and outputs) will be retained indefinitely.

It is anticipated that the results of this research project will be published and/or presented in various forms. Information will be provided in any publication and/or presentation so you cannot be identified.

What will happen if I decide to withdraw?

Your participation in this research is voluntary, and you are free to withdraw from the study anytime without needing to provide any explanation. You would not receive any penalty or bias due to your withdrawal. Should you decide to withdraw and tick the relevant box in your Consent Form, all the information collected from/about you will be destroyed and not used in the research. Please note that you will be able to withdraw your data before the completion of all parts of the project. After this point, you cannot withdraw your data as any links with identifying information will have been destroyed. If you choose to withdraw, contact the research team by email at **drugdrivingenforcement@uq.edu.au**. Upon indicating your intention to withdraw, the researcher will send you a withdrawal form. Please complete and return that withdrawal form. You will receive partial reimbursement for the time you have already contributed.

Can I hear about the results of this research?

Yes, you are very welcome to learn about this study's results. Once the research is complete, we will summarise the main findings through The University of Queensland's research pages. This website will include project updates, key results, links to published journal articles or reports, and presentations at national and international conferences. You will be able to visit these sites to read about what we discovered:

Please note that we will only report results at the group level. This means the data will be averaged across all participants and presented in a way that does not identify you personally. Because this study does not produce individual-level health or clinical feedback, we will not provide personal results to participants. If you would like to receive a direct update or have any questions about the results once they are available, please contact the lead researcher, Dr Shamsi Shekari, at the University of Queensland.

Who can I contact if I have any concerns about the project?

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. You are free to discuss your participation in this study with the researcher, who is contactable at 0438546409 or drugdrivingenforcement@uq.edu.au.

If you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on +617 3365 3924 / +617 3443 1656 or email humanethics@research.uq.edu.au

This research Ethics Approval Numbers – UQ: 2025/HE000945; UTAS: 2025/H40445.

Thank you for your interest in this study and for taking the time to read this information sheet. This information sheet is for you to keep. If you wish to participate in this study, you will be asked to sign a written consent form.