Thank you for your interest in our research study that is investigating the long-lasting effects of methamphetamine on health. Below is the participant information sheet which contains a full description about the questionnaires and tests involved. Please contact Elio Arruzza (Elio.Arruzza@unisa.edu.au or 83021241) if you would like to participate.

Participant Information Sheet

Title	Long-lasting effects of methamphetamine on health
Short Title	Long-lasting effects of methamphetamine on health
Protocol Number	038244
Project Sponsor	University of South Australia
Coordinating Principal Investigator	Associate Professor Gabrielle Todd
Other Investigators	Mr Elio Arruzza, Mr Shayne Chau, Ms Thi (Haley) Vu (UniSA) A/Prof Robert Wilcox (Flinders Medical Centre and Neurology SA) A/Prof Marc Agzarian (South Australia Medical Imaging, Flinders Medical Centre) Professor Adam Vogel (University of Melbourne)
Location	University of South Australia, Neurology SA, and Flinders Medical Centre

Part 1 What does my participation involve?

1 Introduction

The aim of the research project is to investigate the long-lasting effects of methamphetamine on health. The research project involves two groups of participants: adults who have used methamphetamine before and adults who have not used methamphetamine before. You are invited to take part in this research project if you are a healthy adult aged 18-50 yrs.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

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

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The aim of the research project is to gain a greater understanding of the long-lasting effects of methamphetamine on health. The results of this research will be used by the student investigator (Elio Arruzza) to obtain a Doctor of Philosophy degree. This research has been initiated by the researcher Associate Professor Gabrielle Todd.

3 What does participation in this research involve?

Your participation will involve completing a series of questionnaires and non-invasive and painless tests of body function during one or more appointments. All participants will be asked to complete an online questionnaire and an appointment at the City East Campus of the University of South Australia (approximately 2.5-3 hrs in duration). Some participants will be asked to complete a neurological examination (30 mins) and/or MRI scan (15 mins) at Flinders Medical Centre on a different day. Further information about the questionnaires and tests are provided below.

Questionnaires and tests completed before or during the appointment at the University of South Australia:

- Screening questionnaire: You will be asked questions about your health and to determine if it is safe for you to have an MRI scan of your brain.

- Drug use questionnaire: You will be asked questions about use of medications, alcohol, tobacco, e-cigarettes, and illicit drugs.
- Urine sample: You will be asked to provide a small sample of your urine for routine drug screening. The result of the urine test will be recorded and your urine sample will then be placed in a biohazard bin (within 10 mins of you providing the sample).
- Other health questionnaires: You will be asked questions about your sleep, vision, mood, physical activity, and gut and bowel function.
- Neuropsychological assessment: You will be asked to perform short tests of memory, thinking, and mood. These tests will include, for example, recalling a short story and a sequence of numbers that will read to you and listing as many words as you can that start with a particular letter (in 1 min).
- Heart rate & blood pressure test: Your heart rate will be measured by attaching non-invasive, stick-on electrodes on your wrists and ankle. Blood pressure will be monitored via a cuff placed on your upper arm. Heart rate and blood pressure will be recorded while you are sitting, lying down, and standing, and while you forcefully breath out. Your breathing rate will also need to be monitored during this time and this will occur by sticking a small sensor on your abdomen (over your clothing).
- Speech test: You will be asked to read a short paragraph, produce a prolonged vowel sound for five seconds, say the days of the week, say an unusual word (e.g., pataka), and to speak about a specific topic for five minutes. Your speech will be recorded using a microphone and specialised equipment.
- Transcranial ultrasound: The appearance of a brain structure called the substantia nigra will be viewed with non-invasive transcranial ultrasound. The ultrasound probe will be placed above your ear. The technique is safe, non-invasive, and painless, and involves using the same ultrasound machine and probe that is used on pregnant women.

<u>Tests completed at the Flinders Medical Centre appointments:</u>

- Neurological examination: A neurologist (Associate Professor Robert Wilcox) will ask you questions about your health, and you will be asked to perform a range of movements (e.g. walking for 5 m, alternating hand movements, and tapping your heel).
- MRI scan: MRI is a safe and non-invasive form of medical imaging. You will be asked to complete a short MRI safety screen (questionnaire) and then to lie inside the MRI scanner for 5-10 mins. The MRI scan is to capture an image of a part of your brain. During the scan, you will need to lie still inside the scanner and to wear earphones to reduce the noise. Some people may experience symptoms of claustrophobia while lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you. Staff can help you to exit the scanner at any time. The MRI scan is for research purposes and will not be used to help diagnose, treat, or manage a particular condition. A specialist (neuroradiologist) will look at your MRI scans for features relevant to the research project. On rare occasions, the neuroradiologist may find an unusual feature where the risk to health is unclear or unknown. The neuroradiologist will notify a neurologist (Associate Professor Robert Wilcox) via telephone and Associate Professor Wilcox will then discuss the finding with you. You will also be advised of this in writing and provided with a letter to take to your family doctor. Associate Professor Wilcox may also include information about further tests and/or treatment. The discovery of such an abnormality can be stressful.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids research staff or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid. You will be reimbursed $30-$50 upon completion of the study. The reimbursement amount depends on the number of appointments that you need to attend ($30 for one appointment, $40 for two appointments, $50 for three appointments). Reimbursement will be by electronic funds transfer within 2-4 weeks of completion of the study.

4 Other relevant information about the research project

A total of 240 participants will take part. This will consist of 120 participants who have used methamphetamine on five or more occasions and 120 participants who have never used methamphetamine.

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

Participation in any research project 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 project at any stage.

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

6 What are the possible benefits of taking part?

The study will not provide you with any direct benefits. The results of the study will increase understanding about the long-lasting effects of methamphetamine use on health. This knowledge could be used in clinical settings and public health campaigns.

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

There are minimal risks and disadvantages associated with participating in this research project. The above described tests are non-invasive, safe, and painless, and are used in routine clinical practice. You should be aware that any information gathered from you could in principle be obtained by court order: that is, it could be required to be handed over to the police and used as evidence in a court of law against you. However, this is very unlikely. We will make every effort to ensure that any information that you provide will remain confidential. A code will be assigned to you prior to the first appointment and any data collected thereafter will be linked to your code (not your name).

There are no proven long-term risks related to the type of MRI scan used in this research project. MRI is considered to be safe when performed at a medical facility with appropriate procedures. The MRI safety questionnaire helps to identify individuals with contraindications for MRI. Individuals with contraindications for MRI will be excluded from participating in the study.

If you find any of the tests or questionnaires distressing, please let the researcher know and the appointment can be stopped. If you require out-of-hours support, please contact Lifeline by phoning 13 11 14.

8 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. You will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team and any collected data from you will be removed from the group data set.

9 Could this research project be stopped unexpectedly?

It is not anticipated that this research project will be stopped unexpectedly.

10 What happens when the research project ends?

At the end of the research project, the information collected will be analysed and prepared for presentation and publication. This may be through peer-reviewed scientific publications, at scientific conferences, and in the format of a thesis. Only de-identified data will be presented and published. A lay summary of group data, and copies of the resultant publications, will be provided to you at the end of the project via post or email.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form, you consent to the named research staff collecting and the above described personal information about you for the research project. Your privacy and confidentiality will be maintained at all times during this project. Any information obtained in connection with this research project that can identify you will remain confidential. You will be assigned a participant number (e.g. MRIMT-001) and all relevant data collected about you will be labelled with this number and not your name. Information will be stored safely and securely in a locked filing cabinet and on password protected computers at the University of South Australia and Flinders Medical Centre. The MRI scans will also be stored in the SA Health Digital Radiology System. Information regarding your medical history will only be used by the researchers working on the study. The results of all tests will not be published in a way that could reveal your identity. All records will be kept for a minimum of 15 years in accordance with the requirements of the Australian Code for the Responsible Conduct of Research (2018), Research Ethics Policy Directive (2020), and General Disposal Schedule No.28. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

In accordance with relevant Australian and South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to

request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

12 Complaints and compensation

If you suffer distress, or injuries including psychological injury or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment and support. If you are eligible for Medicare, you can receive any medical treatment required to treat the issue, free of charge, as a public patient in any Australian public hospital.

13 Who is organising and funding the research?

The research project is being organised by Associate Professor Gabrielle Todd (University of South Australia). The University of South Australia has contributed funding towards the cost of performing the research project. The researchers are submitting applications to other medical and scientific funding bodies to cover the remaining direct research costs. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 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 the HREC of the University of South Australia and Southern Adelaide Clinical Human Research Ethics Committee. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007), updated in 2018. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 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 problems which may be related to involvement in the project, please contact:

Research contact person

Name	*Associate Professor Gabrielle Todd*
Position	*Associate Professor of Neuroscience, University of South Australia*
Telephone	*(08) 8302 1979*
Email	*Gabrielle.Todd@unisa.edu.au*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	*Southern Adelaide Local Health Network*
Position	*Manager, Research Governance and Ethics*
Telephone	*8204 6453*
Email	*Health.SALHNOfficeforresearch@sa.gov.au*

If you have any complaints about any aspect of the project, the way it is being conducted, or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Southern Adelaide Clinical*
HREC Executive Officer	*Executive Officer*
Telephone	*8204 6453*
Email	*Health.SALHNOfficeforResearch.sa.gov.au*

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*Southern Adelaide Clinical*
Position	*Research Governance Officer*
Telephone	*8204 6453*
Email	*Health.SALHNOfficeforResearch.sa.gov.au*