Participant Information Sheet/Consent Form

St Vincent's Hospital Sydney

Title	S-Check 2.0 cohort study: a smartphone application for methamphetamine use
Short Title	S-Check 2.0 Cohort Study
Protocol Number	2024/ETH01154
Project Sponsor	St Vincent's Hospital Sydney
Principal Investigator	Dr Krista Siefried
Associate Investigator(s)	Nadine Ezard, Brendan Clifford, Dora Karavasilis, Seb Baird, Stephanie Riches-Evans, Kathryn Fletcher, Liam Acheson, Florence Bascombe, Nicky Bath, Daniel Herman, Jack Freestone, Elizabeth Knock, Mike Millard, Peter Middleton, Maureen Steele, John G
Location	St Vincent's Hospital Sydney

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have identified yourself as someone who has used methamphetamine within the past month. The research project is testing a new Smartphone App (S-Check 2.0) that provides self-assessments, risk identification, education, tips and resources for people using methamphetamine. This information sheet tells you about the research project. It explains the app and what your participation will involve. 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. You can email the research team on Scheckapptrial@nccred.org.au if you have any questions. Before deciding whether to take part, you might want to talk about it with a relative, friend or your 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 tick the "I agree to participate box". By doing so, you are telling us that you:
• Understand what you have read
• Consent to take part in the research project and
• Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

The S-Check 2.0 app has been developed as a tool to engage people who use methamphetamine who are not seeking traditional modes of treatment. It provides the app user with information on methamphetamine and the risks and harm associated with methamphetamine use. It is also intended to increase the app user's self-awareness of their personal risk and harm associated with methamphetamine use.

The main aim of this research project is to understand more about those who use the app, and whether the app can motivate change in people who use methamphetamine, influence their methamphetamine use and other mental health outcomes.

This research has been initiated by Professor Nadine Ezard, Clinical Director of the St Vincent's Hospital Sydney Alcohol and Drug Service. It is funded by the National Centre for Clinical Research on Emerging Drugs (NCCRED).

3 What does participation in this research involve?

If you agree to participate, there will be some questions asking about you and your use of methamphetamine. This is to make sure you are eligible to participate and that the research project is suitable for you. If you are eligible to participate, you will be given immediate access to the full features of the S-Check 2.0 App. You will first be asked to complete some mandatory questions (demographics, methamphetamine use, help-seeking). You will then have access to optional self-assessments to help you understand the impact of methamphetamine on your broader health and wellbeing; a tracking feature to log your methamphetamine use, overall mood and sleep quality; and tailored suggestions for resources and further support. You will be able to choose how often you would like to be notified for check-ins.

Every 28 days, you will be asked some mandatory brief questions about any changes you have made. You can continue using the app as often as you like until the research study ends, at which point the app will no longer be available (July 2026).

We will be collecting information on how often you use the app and what features of the app are being used. The data collection process is inbuilt into the app, so there will be no need to contact you as you use the app.

4 What do I have to do?

You have installed the S-Check 2.0 App on your phone. You need to carefully read this information sheet and indicate your consent to participate by selecting the "I agree to participate" box at the end of this section. You will then be provided with full access to the app. An electronic version of this information sheet will be available for you to download from the app.

5 Other relevant information about the research project

You will be participating in a single group study. In this study, all participants receive the same treatment. This study has been designed to make sure the researchers interpret the results in a fair and appropriate way. There are no additional costs associated with participating in this research project. This research involves collaboration with researchers from St Vincent's Hospital Sydney and the University of New South Wales.

6 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.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with those involved in the research project or your relationship with St Vincent's Hospital, Sydney or any of the other institutions participating in this research.

7 What are the alternatives to participation?

You do not have to take part in this research project to seek or receive support or treatment. Other options are available including contacting your local hospital or doctor. If you would like more support with your substance use, please contact:

- The National Alcohol and Other Drug Hotline: 1800 250 015
- St Vincent's Alcohol and Drug Service Centralised Intake line: (02) 8382 1080 (if residing in Sydney)
- St Vincent's Stimulant Treatment Line: (02) 8382 1111
- Lifeline: 13 11 14
- Alcohol and Drug Counselling Online: https://www.counsellingonline.org.au/
- In the case of emergency: 000

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include your improved awareness of your use of methamphetamine and treatment and support services available following the use of the S-Check App.

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

Although the research team does not expect any risk, there may be side effects that the researchers did not expect or did not know about. If you become upset or distressed as a result of your participation in the research, please email the research team on Scheckapptrial@nccred.org.au. This email is checked once daily during business hours only (Monday to Friday, 9am-5pm AEST). The S-Check app and study email is not a crisis response service and does not replace your usual clinical or psychosocial care.

10 Can I have other treatments during this research project?

The S-Check 2.0 App has been developed to help motivate change. You can have other treatments during this research project.

11 What if I withdraw from this research project?

If you decide to withdraw from the project, you will need to delete the app from your phone. Deletion of the app indicates to us that you have decided to withdraw from the project. If you do withdraw your consent during the research project, no additional information will be collected, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

12 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• The S-Check 2.0 App has been shown not to be effective
• The S-Check 2.0 App has been shown to work and not need further testing

13 What happens when the research project ends?

The research team hopes to publish and present the results in peer-reviewed medical journals and at conferences. If the results are favourable, the S-Check 2.0 App will be available for use to the wider community.

Should you wish to know about the results of the research, please email Scheckapptrial@nccred.org.au and the research team will provide you information at the end of the project.

Part 2 How is the research project being conducted?

14 What will happen to the information about me?

By ticking the "I agree to participate" box, you consent to the relevant research staff collecting and using personal information about you for the research project. No identifiable information will be collected from you. You will be assigned a unique study number. This unique study number will be used in all data analysis and reporting. Your information will be kept in a secure location at St Vincent's Hospital, Sydney. Access to your information will only be provided to the research team. 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.

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, St Vincent's Hospital, Sydney, the institution relevant to this Participant Information Sheet, or as required by law. By ticking the "I agree to participate" box, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

After the study has been completed, all study-related documents will be stored securely for 15 years in line with national research guidelines, and then securely destroyed. Emails provided to the research team when assistance is requested will be permanently deleted once assistance is completed.

15 Complaints and compensation

If you suffer any complications as a result of this research project, you should email the study team as soon as possible at Scheckapptrial@nccred.org.au. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You may also be able to seek compensation through the courts.

16 Who is organising and funding the research?

This research project is being conducted by Professor Nadine Ezard, St Vincent's Hospital Sydney. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 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 St Vincent's Hospital, Sydney (HREC number: 2024/ETH01154)

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

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

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can email: Scheckapptrial@nccred.org.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	Research Office Manager
Position	*Research Office Manager*
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.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 Dr Pamela Blaikie on 02 8382 4960 or email: SVHS.Research@svha.org.au.

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital, Sydney
HREC Research Officer	HREC Research Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

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

Name	Research Governance Officer
Position	Research Governance Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

ST VINCENT'S HOSPITAL SYDNEY
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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Coordinating Principal Investigator/ Principal Investigator	Dr Krista Siefried
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Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

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

I give permission to the research team to use the data that have been collected through the S-Check 2.0 App for the purposes of this research project. I understand that such information will remain confidential.

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

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care. Should I wish to withdraw, I will email the research team on Scheckapp@nccred.org.au.

☐ I agree to participate. An electronic version of this Participant Information Sheet and Consent form will be available on S-Check 2.0 App for you to download.

☐ I do not wish to participate.