Participant Information Sheet/Consent Form

St Vincent's Hospital Sydney

Title	Feasibility of efficacy of the S-Check App: a harm reduction and early intervention smartphone application for methamphetamine use
Short Title	S-Check App Trial
Protocol Number	18/171
Project Sponsor	St Vincent's Hospital Sydney
Coordinating Principal Investigator/ Principal Investigator	A/Prof Nadine Ezard
Associate Investigator(s)	Peter Middleton, Daniel Herman, Victoria Malone, Quoc Nguyen, Krista Siefried, Francis Kay-Lambkin
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 App) that provides self-assessments, risk identification, education, tips and resources for people using methamphetamine. This Participant Information Sheet/Consent Form 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. Before deciding whether or not 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" and to provide some information about yourself (such as your name, and mobile number). 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 as described.

2 What is the purpose of this research?

The S-Check App has been developed as a tool to engage methamphetamine users 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 of this research project is to assess whether the S-Check app can motivate change in people who use methamphetamine.

This research has been initiated by the study doctor, A/Prof Nadine Ezard, Clinical Director of the St Vincent's Hospital Sydney Alcohol and Drug Service. It is funded by a grant provided by the NSW Ministry of Health and by Commonwealth Department of Health.

3 What does participation in this research involve?

If you wish to participate, you will be participating in a randomised wait-controlled research project. We would like to find out whether the S-Check App can motivate change by comparing a group that will have immediate access to the App and a group that will have access to the App after 28 days. The results from both groups are compared to see if one is better than the other. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You have downloaded the S-Check App onto your smartphone. 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. You will then be asked some questions about yourself and how you are. This is to collect some information at the start of the research. Then depending on how you are randomised, you will either be given immediate access to the full features of the S-Check App or be sent weekly reminders that the App will be fully functional in the next 28 days. Once you have full access of the App, weekly reminders are sent to remind you of the features of the App to encourage you to use it.

If you are given immediate access to the App, you will be again asked questions about yourself and how you are at 28 days. You will also be asked questions about your thoughts on using the S-Check App. You will then be able to use the App for the next 28 days, after which it will be become disabled.

If you are given access to App after the 28 day wait time, you will be asked again questions about yourself and how you are. This is to see if any changes have occurred since you agreed to participate. You will then have full access to the App for the next 28 days. At Day 56, we will be asking you some questions about your thoughts on using the App. The App will become disabled after this time.

You can also volunteer to participate in a telephone interview that will be conducted after 28 days of using the App. The interview will last for 30 minutes and will ask for your opinion and experience about using the App. The telephone interview will be recorded to assist us to review your responses. To volunteer, you need to provide the research team with your telephone number.

In both groups, 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. The App will be available for you use for a further 28 days before it becomes disabled.

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

Reimbursements

There are no additional costs associated with participating in this research project nor will you be paid to participate. You will however, be reimbursed with a $20 online egift card for completing the survey at the start of the research and a $25 online egift card for completing the survey at 28 days. A $20 online egift card will be provided to those who participate in the telephone interview.

4 What do I have to do?

You have installed the S-Check App on your smart phone. You need to carefully read this electronic version of this patient information sheet and indicate your consent to participate by ticking the "I agree to participate" box at the end of this section. You will then be either provided with full access to the S-Check App or sent weekly reminders that the App will be available in 28 days' time. An electronic version of this participant information sheet and consent form will be available for you to download from the S-Check App.

5 Other relevant information about the research project

The research project will be recruiting 1020 participants like yourself to participate. 510 will have access have immediate access to the S-Check App while 510 will be access after 28 days. The research is being conducted by the Alcohol and Drug Services of St Vincent's Hospital Sydney. The University of New South Wales, Sydney and the University of Newcastle are also assisting with participant recruitment, the conduct of the interviews and data management.

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, drug addiction helpline line or your local doctor.

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 the 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.The study doctor may be able to arrange for counselling or other appropriate support services.

10 Can I have other treatments during this research project?

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

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please email a member of the research team on Scheckapptrial@nccred.org.au. If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal 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. If you do not want them to do this, you must tell them before you join the research project.

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

14 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 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?

15 What will happen to the information about me?

By ticking the "I agree to participate" box, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. You will be assigned a unique study number which will replace any identifiable information. 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. Your information will be kept for a period of seven years before it is destroyed.

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 St Vincent's Hospital, 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, except with your permission.

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.

16 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.

17 Who is organising and funding the research?

This research project is being conducted by A/Prof Nadine Ezard, St Vincent's Hospital Sydney through research grants provided by the NSW Ministry of Health and the Commonwealth Department of Health. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18 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 No HREC/18/SVH/196)

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 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

Consent Form

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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 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 Scheckapptrial@nccred.org.au.

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

☐ I do not wish to participate.

Telephone Interview:
We are also asking people who use the App to participate in a 30 minute telephone interview to discuss the App.

☐ Yes, I wish to participate in the telephone interview. I give my permission to participate in a 30 minute telephone interview and understand that it will be recorded. My contact details are:
Name: _____
Telephone number is: _____

☐ No, I do not wish to participate in the telephone interview.