



20 September 2018

A/Prof Nadine Ezard
St Vincent's Hospital Drug and Alcohol Service
Level 6, O'Brien Building
Darlinghurst NSW 2010

Dear Nadine

SVH File Number: 18/171

Project Title: Feasibility and efficacy of the S-Check App: A harm reduction and early intervention smartphone application for methamphetamine use

HREC Reference Number: HREC/18/SVH/196

Thank you for your letter, dated **22 August 2018**, responding to issues raised regarding the above project, which was first considered by the St Vincent's Hospital HREC at its meeting held on **9 August 2018**.

This project meets the requirements of the National Statement on Ethical Conduct in Human Research. I am pleased to advise that the Committee at an Executive meeting on **19 September 2018** has granted ethical and scientific approval of the above **multi centre** project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note that it is not considered best practice to store research data on personal hardware. No identifiable participant data can leave a site. There always needs to be data security measures in place and a clear plan for permanent destruction of data needs to be adhered to at completion of the project.

The project is approved to be conducted at:

- St Vincent's Hospital, Sydney
- University of New South Wales

Please note the addition of The University of Newcastle is pending receipt of a fully executed External Entity Agreement.

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

**St Vincent's Hospital
Sydney Limited
ABN 77054038872**

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The following documentation has been reviewed and approved by the HREC:

- Protocol, Version 1.0, dated 12 June 2018
- Participant Information Sheet and Consent Form, Version 2.0, dated 14 August 2018
- S-Check App Trial Advertisement, Version 1.1, dated 26 August 2018

The Human Research Ethics Application Form (HREA) document reviewed by the HREC was HREA **AU/1/941835**.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **19 September 2023**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report beginning in **September 2019**, to the HREC as well as a final study report at the completion of the project in the specified format.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg. Australian Clinical Trial Registry <http://www.anzctr.org.au/> and <https://clinicaltrials.gov/>).

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

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Should you have any queries regarding this project please contact the Research Office, Tel: 8382-4960, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: <https://svhs.org.au/home/research-education/research-office>

St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

Please quote **SVH File Number: 18/171** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Monica Logan', with a long horizontal line underneath.

Monica Logan
Research Officer
St Vincent's Hospital Research Office
Translational Research Centre, 97-105 Boundary Street

cc: Quoc Nguyen
TRIM REF: D/2018/67904

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5 October 2018

A/Prof Nadine Ezard
St Vincent's Hospital Drug and Alcohol Service
Level 6, O'Brien Building
Darlinghurst NSW 2010

Dear Nadine

SVH File Number: 18/171

Project Title: Feasibility and efficacy of the S-Check App: A harm reduction and early intervention smartphone application for methamphetamine use

HREC Reference Number: HREC/18/SVH/196

Thank you for submitting a request for an amendment dated **5 October 2018** to the above project. This was considered by the St Vincent's Hospital HREC at its Executive meeting held out of session on **5 October 2018**.

I am pleased to advise that the document reviewed and approved at the meeting was:

- Participant Information Sheet and Consent Form, Version 3.0, dated 5 October 2018

As indicated by the amendment application form, the Coordinating/Principal Investigator has declared that no governance authorisation for the following site/s has been granted by St Vincent's Hospital Research Office:

- **St Vincent's Public Hospital (includes Sacred Heart Hospice and St Joseph's Hospital)**

You must not commence this research project at any site/s subject to review by St Vincent's Hospital Research Office until a completed Site Specific Assessment Form with associated documentation has been submitted to the site Research Governance Officer and authorised.

You are reminded that this letter constitutes ongoing ETHICAL and SCIENTIFIC review only. For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents prior to implementation of the amendment.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Tel: (02) 8382-4960, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website found at: <https://svhs.org.au/home/research-education/research-office>

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St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

Yours sincerely,

A handwritten signature in black ink that reads "Patricia Kenny".

Patricia Kenny

Research Officer

St Vincent's Hospital Research Office

Translational Research Centre, 97-105 Boundary Street

cc: Quoc Nguyeb

TRIM REF: D/2018/76407

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20 March 2019

A/Prof Nadine Ezard
St Vincent's Hospital Drug and Alcohol Service
Level 6, O'Brien Building
Darlinghurst NSW 2010

Dear Nadine

SVH File Number: 18/171

Project Title: Feasibility and efficacy of the S-Check App: A harm reduction and early intervention smartphone application for methamphetamine use

HREC Reference Number: HREC/18/SVH/196

Thank you for submitting a request for an amendment dated **8 March 2019** to the above project. This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **19 March 2019**.

I am pleased to advise that the documents reviewed and approved at the meeting were:

- S-Check App Trial Protocol Version 2.0, dated 5 October 2018
- S-Check App Trial SVH Participant Information Sheet and Consent Form Version 4.0, dated 11 January 2019

The HREC Executive also noted the following:

- Noted registration of an external HREC Approval from the University of Newcastle letter dated the 25th Jan 2019 Refer No. H-2019-0016

This amendment has also been reviewed and noted by the Research Governance Officer at St Vincent's Hospital. Further review of the approved documents is not required for any authorised site for which the St Vincent's Hospital Research Office conducts research governance. Implementation of this amendment can now proceed at this site.

Please note that this letter constitutes ongoing ETHICAL and SCIENTIFIC review only. For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents prior to implementation of the amendment.

Should you have any queries regarding this project please contact the Research Office, Tel: (02) 8382-4960, email SVHS.Research@svha.org.au. Further relevant information is available on the Research Office website found at: <https://svhs.org.au/home/research-education/research-office>

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Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Larran O'Shea'.

Larran O'Shea
Research Officer
St Vincent's Hospital Research Office
Translational Research Centre
97-105 Boundary Street
Darlinghurst NSW 2010

cc: Quoc Nguyen
TRIM REF: D/2019/17449

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