


## 2024/ETH01154: Application HREA - Approved

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Mon 8/12/2024 7:36 PM

To: Krista Siefried <krista.siefried@svha.org.au>

Cc: Seb Baird <seb.baird@unsw.edu.au>; Brendan Clifford <Brendan.Clifford@svha.org.au>; Nadine Ezard (Redirection) <Nadine.Ezard@svha.org.au>; Kathryn Fletcher <k.fletcher@unsw.edu.au>

 2 attachments (173 KB)

S-Check 2.0\_PISCF V3.0 9 August 2024\_clean.docx.docx; S-Check 2.0\_PISCF V3.0 9 August 2024\_tracked.docx.docx;

Date of Decision Notification: **12 Aug 2024**

Dear Krista Siefried,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;  
**2024/ETH01154: S-Check 2.0 cohort study: a smartphone application for methamphetamine use**

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **St Vincent's Hospital Human Research Ethics Committee** at its meeting held on **4 July 2024**.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2023) and was **APPROVED**.

**This email constitutes ethical and scientific approval only.**

**This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.**

This project has been Approved to be conducted at the following sites:

- **St Vincent's Health Sydney**

The following documentation was reviewed and is included in this approval:

- Project Registration
- Submission Cover Letter\_19Jun2024
- HREC Cover\_SCheck\_Response1\_31July2024
- HREC Cover\_SCheck\_Response2\_9Aug2024
- S-Check 2.0\_Measures, version 2.0, 23 July 2024\_tracked and clean
- **S-Check 2.0\_PISCF, version 3.0, 9 August 2024\_tracked and clean\*\***
- S-Check 2.0\_Protocol, version 3.0, 9 August 2024\_tracked and clean
- S-Check2.0\_Study advert V1.0, version 1.0, 19 June 2024

**\*\*The version number and date in the consent form was not aligned with the rest of document headers and were corrected. Please find attached the PISCF for implementation once the site is authorised. The corrected documents were also uploaded in REGIS and made visible to you in your portal.**

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was: Version: 1.02 Date: 09 Aug 2024

The approval is for a period of 5 years from the date of this e-mail **(12 Aug 2024)**

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
- **Interventional trials must be registered on one of the clinical trial registries e.g. <https://www.anzctr.org.au>.**

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#).

It is noted that the **St Vincent's Hospital Human Research Ethics Committee** is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2023 (NHMRC).

We look forward to managing this study with you throughout the project lifecycle.

Regards,

Geraldine Bicol (On behalf of the St Vincent's Hospital Human Research Ethics Committee)  
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