

## Gideon Caplan (South Eastern Sydney LHD)

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**From:** no\_reply@regis.health.nsw.gov.au  
**Sent:** Wednesday, 30 November 2022 3:05 PM  
**To:** Gideon Caplan (South Eastern Sydney LHD)  
**Subject:** 2022/ETH02280: Application HREA - Approved

Date of Decision Notification: 30 Nov 2022

Dear Professor Gideon Caplan,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2022/ETH02280:** World Delirium Awareness Day (WDAD) 1-day point delirium prevalence study

This Application was reviewed as a **Low or negligible risk review pathway** and was initially considered by the **South Eastern Sydney Local Health District HREC** at its meeting held on **08 November 2022**.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) 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:

- Prince of Wales Hospital
- Southern Cross University
- Armadale Kalamunda Group
- Southern Adelaide LHN
- Caboolture Hospital
- Cairns Hospital

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

- Study Protocol, version 1.3, dated 21/11/2022 (filename: Delirium Prevalence Survey WDAD v1\_3 20221121 CLEAN.docx)
- Application, HREA
- Letter of Invitation, version 1.1, dated 01/10/2022 (filename: Delirium Prevalence Survey WDAD Participant Invitation Letter v1\_1 20221001.docx)
- Principal Investigator Questionnaire, version 1.0, dated 01/10/2022 (filename: Data collection form Investigator v1\_0 20221001.docx)
- Ward Questionnaire version 1.0, dated 01/10/2022 (filename: Data collection form Ward v1\_1 20221001.docx)

[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: 1.01

Date: 22 Nov 2022

The approval is for a period of 5 years from the date of this e-mail (**30 Nov 2022**)

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.

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 **South Eastern Sydney Local Health District HREC** is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2007 (NHMRC).

The processes used by the HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Regards,

Sophie Gates  
Research Ethics and Governance Officer  
SESLHD-RSO@health.nsw.gov.au