

## Ashwani Kumar

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**From:** no\_reply@regis.health.nsw.gov.au  
**To:** akumar@georgeinstitute.org.au  
**Cc:** akumar@georgeinstitute.org.au;swslhd-ethics@health.nsw.gov.au  
**Subject:** 2020/ETH00180: Application HREA - Approved

Date of Decision Notification: **14 May 2020**

Dear Ashwani Kumar,

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

**2020/ETH00180:** Validation of ICD codes in estimating sepsis epidemiology: A prospective, observational cohort study

This project was considered by the **South Western Sydney Local Health District Human Research Ethics Committee** and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

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

- Campbelltown Hospital
- Liverpool Hospital
- Bankstown-Lidcombe

**\*\*Please submit the STE application in REGIS for the above sites\*\***

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

- Human Research Ethics Application, Version 2.0, 14.04.2020
- Protocol, Version 1.6, 11.05.2019

[Application Documents](#) - (Please note : Due to security reasons, this link will only be active for 14 days.)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.01

Date: 12 May 2020

It is noted that the South Western Sydney Local Health District Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC). The approval is for a period of **5 years from the date of this e-mail (14 May 2020)** , on condition of the submission of Annual Reports.

We wish you all the best with the project and remind you that any changes to the application and safety reports will need to be submitted and reviewed by the approving HREC prior to implementation.

**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 under whose auspices the research will be conducted at that site.

**This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007). The processes used by this 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 application with you throughout the project lifecycle.

Please note the following conditions of approval:

**\*\*Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are followed until the restrictions have been lifted\*\***

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
1. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
1. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
1. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
1. The Principal Investigator must reassure participants about confidentiality of the data.
1. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
1. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from: <https://www.swslhd.health.nsw.gov.au/ethics/policies.html>

Should you have any queries about your project please contact **Andrea Lee** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <https://www.swslhd.health.nsw.gov.au/ethics/>

Please quote the Local HREC reference **2020/ETH00180** in all correspondence. The HREC wishes you every success in your research.

Yours faithfully

**Miss Andrea Lee**

*on behalf of*

**A/Professor Murray Killingsworth**

Chairperson, SWSLHD Human Research Ethics Committee

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Kind regards,

**Andrea Lee**

A/Research Ethics and Governance Manager | **Research Directorate**

South Western Sydney Local Health District (SWSLHD)

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**Use REGIS for all Research Applications**

The Research and Ethics Office is using [REGIS](#) for all Research Applications (HREA and SSA).