

Moein Mehrolhassani

From: moein.mehrolhassani@unimelb.edu.au
Subject: FW: Ethics Approval!

From: no_reply@regis.health.nsw.gov.au <no_reply@regis.health.nsw.gov.au>
Sent: Monday, May 15, 2023 4:35 PM
To: Tracy Baylis <tracy.baylis@unimelb.edu.au>
Cc: cinsw-ethics@health.nsw.gov.au
Subject: [EXT] 2022/ETH00905: Application HREA - Approved

External email: Please exercise caution

Date of Decision Notification: 15 May 2023

Dear Ms Tracy Baylis,

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

2022/ETH00905 / 2022.12: Australian Urban Health Indicators (AusUrb-HI): Urban Heat, Liveability and Health study

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **NSW Population and Health Services Research Ethics Committee** at its meeting held on **12 April 2023**.
The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (NH&MRC, 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:

- Australian Urban Observatory (AUO), RMIT University Melbourne City Campus VIC (Access to Unit Record Data Y)
- Australian Urban Research Infrastructure Network (AURIN), University of Melbourne VIC (Access to Unit Record Data Y)
- School of Population and Global Health, The University of Western Australia WA (Access to Unit Record Data Y)

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

- Cover Letter
- Letter of Response, dated 30 April 2023
- Human Research Ethics Application 2022/ETH00905 version 3, dated 21 April 2023
- Combined Protocol and Application for Data - PHSREC version 1.5, dated 30 April 2023
- NSW Privacy Form
- NSW Statewide Data Collections:
 - Admitted Patient Data Collection (APDC) Variable List version 1.1, dated 3 March 2023
 - Emergency Department Data Collection (EDDC) Variable List, dated 3 March 2023
 - APDC and EDDC Data Custodian Approval, dated 31 March 2023

- Register of Births, Deaths and Marriages (RBDM) – Death Registrations Variable List version 1, dated 3 March 2023
- Cause of Death Unit Record File (COD-URF) Variable List version 1.1, dated 3 March 2023
 - RBDM and COD-URF Data Custodian Approval, dated 16 January 2023
- CHeReL Technical Feasibility Letter/Email - CHeReL ID#2022.12, dated 25 July 2022
- Associate Professor Melanie Davern CV
- Dr Derrick Lopez CV
- Dr Hao Chen CV
- Dr Fadhillah Norzahari CV
- Ms Flavia Barar CV
- Professor David Preen CV
- Ms Tracy Baylis CV
- Independent Peer Review Report, dated 25 May 2022
- Study Area Geocode
- Analysis Plan
- Justification for SA1 Data

The approval is for a period of 5 years from the date of this e-mail (**15 May 2023**)

The Committee granted a waiver of the usual requirement of consent for the use of re-identifiable information in accordance with Section 2.3 of the National Statement on Ethical Conduct in Human Research. This includes information held by NSW agencies, in line with the State Privacy Commissioner's Guidelines for Research and the Health Records and Information Privacy Act 2002 (NSW).

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](#).

The **NSW Population and Health Services Research Ethics Committee** is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (NH&MRC, 2007).

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,

Secretariat on behalf of David Roder, Chairperson, NSW Population and Health Services Research Ethics Committee

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We acknowledge the traditional custodians of the lands on which we work and live,
and pay our respect to Elders past, present and future.

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