Human Research Ethics Application

Application Management Information

Application ID: 2022/ETH00905

Created date: 21/04/2023

Originating Application ID: 2022/ETH00905

\*This is the earliest application from which this application (2022/ETH00905) was copied.

Parent Application ID: 2022/ETH00905

\*This is the immediate predecessor from which this application (2022/ETH00905) was copied.

Version Number: 3

Application submitted to: Cancer Institute NSW; NSW Population and Health Service Research Ethics Committee.

The applicant has requested that this ethics application be considered under the Greater than low risk review pathway.

Section 1 – Core Information

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the [National Statement](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018).
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

**Q1.1 Project Title:**

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| --- |
| Australian Urban Health Indicators (AusUrb-HI): Urban Heat, Liveability and Health study |

**Q1.2 Summary of the research project:**

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| --- |
| The Australian Urban Health Indicators (AusUrb-HI) project will develop new indicator data assets to improve our understanding of the health of urban populations and identify incidence patterns and key risk factors across the population. The project looks at health-related outcomes due to heat vulunerablity and urban liveability. It will integrate health, socio-economic, environmental, climate and built environment datasets to provide a holistic spatially-explicit understanding of urban population health. These indicators will allow health, urban and social infrastructure planners and policy makers to develop targeted policies and actions, and the outcomes will be shared with the research community. |

**Q1.3 Which category/ies of research best describes the project?**

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| --- |
| Public Health and Health Services - 1117 |

**Q1.4 In what environments will the research be conducted?**

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| --- |
| Research institute(s)  University(ies) |

**Q1.5 What organisation/entity has overall responsibility for this project?**

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| --- |
| Sponsor type: Collaborative group  Sponsor name: AURIN |

**Q1.6 Describe how this research project is currently, or will be, funded.**

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| --- |
| This project is funded to the amount of $400,000 by the Australian Research Data Commons |

**Q1.7 Anticipated starting date of the research project:**

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| --- |
| As soon as ethics and any other relevant approvals have been provided. |

**Q1.8 Anticipated duration of the research project:**

|  |
| --- |
| 4 Years |
|  |

Project Team

*Name:*  **Tracy Baylis**

**Q1.9.4 Email Address:**

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| --- |
| tracy.baylis@unimelb.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

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| --- |
| Yes |

|  |  |
| --- | --- |
| **Q1.9.5.1 Email Address:** | tracy.baylis@unimelb.edu.au |
| **Q1.9.5.2 Telephone Number:** | ​0417333673 |
| **Q1.9.5.3 Mailing Address** | AURIN, Level 3 Thomas Cherry Building, The University of Melbourne, Corner Swanston and Elgin Street, Victoria 3010 |

**Q1.9.6 Is this person a student on this project?**

|  |
| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

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| --- |
| Australian Urban Research Infrastructure Network (AURIN) Strategic Planning & Implementation Manager |

**Q1.9.8 Staff ID** *(optional)***:**

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| --- |
| ​141729 |

**Q1.9.9 ORCID Identifier** *(optional)***:**

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**Q1.9.10 Position on the research project:**

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| --- |
| Co-ordinating Principal Investigator/Researcher |

**Q1.9.12 Research activities Tracy Baylis** **will be responsible for:**

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| --- |
| Tracy will provide project/research governance, leadership and advice. |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| Ms Baylis has extensive experience in managing health and research infrastructure facilities. She is responsible for the strategic delivery of eResearch infrastructure to support internationally leading urban, regional, and social science research and managing collaborative research infrastructure projects such as the Australian Urban Health Indicators project (AusUrb-HI). |

*Name:*  **Melanie Davern**

**Q1.9.4 Email Address:**

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| --- |
| melanie.davern@rmit.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

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| --- |
| No |

**Q1.9.6 Is this person a student on this project?**

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| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

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| --- |
| Associate Professor at RMIT University, Director Australian Urban Observatory & Acting Deputy Director of the Centre for Urban Research |

**Q1.9.8 Staff ID** *(optional)***:**

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**Q1.9.9 ORCID Identifier** *(optional)***:**

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| ​0000-0002-3790-0024 |

**Q1.9.10 Position on the research project:**

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| --- |
| Principal Investigator |

**Q1.9.12 Research activities Melanie Davern** **will be responsible for:**

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| --- |
| Professor Davern will provide project/research governance, leadership and advice, as well as data analysis as per the described methodologies. |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| A/Prof Davern is a public health and urban planning academic and Vice Chancellor’s Senior Research Fellow at RMIT University with extensive experience in developing and analysing large scale administrative health survey data including geocoded Victorian Population Health Survey data with supported ethical clearance from the Victorian Department of Health. As Co-Lead of a program of research investigating Health, Place & Society with Professor Hannah Badland, A/Prof Davern has also produced spatial measures of the built and natural environments linked to existing health data sets including the Australian Early Development Census and Longitudinal Study of Australian Children held by the Australian Institute of Family Studies. |

*Name:* **Dr Derrick Lopez**

**Q1.9.4 Email Address:**

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| --- |
| Derrick.Lopez@uwa.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

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| --- |
| No |

**Q1.9.6 Is this person a student on this project?**

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| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

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| --- |
| Research Fellow, The University of Western Australia |

**Q1.9.8 Staff ID** *(optional)***:**

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**Q1.9.9 ORCID Identifier** *(optional)***:**

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| ​0000-0003-0677-0420 |

**Q1.9.10 Position on the research project:**

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| --- |
| Associate/Assistant/Sub-/Co- Investigator/Researcher |

**Q1.9.12 Research activities Dr Derrick Lopez** **will be responsible for:**

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| --- |
| Dr Lopez will provide advise on the analysis of linked data |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| Dr Lopez is a Research Fellow at the School of Population and Global Health, The University of Western Australia.  He has been involved with conducting epidemiological studies and health services research with Australian and international researchers using administrative population-level linked data in many areas including cardiovascular disease, pharmacoepidemiology, healthy ageing and frailty, and rural health for more than 10 years.  He is also involved in teaching the *Introductory Analysis of Linked Health Data* and *Advanced Analysis of Linked Health Data* courses at The University of Western Australia.    Examples of Dr Lopez's experience with linked data:   1. Currently working on WA Health approved project project titled: “Services provided and outcomes for patients suspected of experiencing a heart attack or stroke and transported by the Royal Flying Doctor Services (RFDS) to hospitals across Western Australia.”.  This project uses unit record linked data from RFDS and WA Health (Hospital Morbidity Data Collection, Emergency Department Data Collection, death registrations, cause of death unit record file). 2. Used unit record linked data from Pharmaceutical Benefits Scheme, WA Health (Hospital Morbidity Data Collection and death registrations) in this manuscript: **Effect of frailty on initiation of statins following incident acute coronary syndromes in patients aged ≥75 years** Lopez D, et al  Nov 2021, In: Maturitas. 153: 13-18;  DOI: <https://doi.org/10.1016/j.maturitas.2021.07.006> 3. Used cohort data from Health in Men Study and unit record linked data from WA Health (Hospital Morbidity Data Collection and death registrations) in this manuscript: **The Hospital Frailty Risk Score identifies fewer cases of frailty in a community-based cohort of older men than the FRAIL Scale and Frailty Index** Lopez D, et al  2 Nov 2021, In: Journal of the American Medical Directors Association. 23(8): 1348-1353.  DOI: <https://doi.org/10.1016/j.jamda.2021.09.033> 4. Used unit record linked data from PBS, WA Health (hospitalisations and death registrations) in this manuscript: **Frailty, and not medicines with anticholinergic or sedative effects, predicts adverse outcomes in octogenarians admitted for myocardial infarction: population‐level study**Lopez D et al  7 Dec 2020, In: Australasian Journal of Ageing. DOI: <https://doi.org/10.1111/ajag.12891> 5. Have accessed unit-record, linked data using SURE from: 1) the 45 and Up Study; 2) NSW Admitted Patient Data Collection; 3) NSW Cancer Registry; 4) Medicare Benefits Schedule claims; 5) Pharmaceutical Benefits Scheme claims; and 6) NSW Registry of Births Deaths & Marriage.  The findings were published in:  **Clinical consultations and investigations before and after discontinuation of endocrine therapy in women with primary breast cancer**Lopez D, et al  1 Jul 2017, In: Public Health Research & Practice. 27 (3): e2731726.  DOI: <https://doi.org/10.17061/phrp2731726> |

*Name:* **Dr Hao Chen**

**Q1.9.4 Email Address:**

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| --- |
| chen.h@unimelb.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

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| --- |
| No |

**Q1.9.6 Is this person a student on this project?**

|  |
| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

|  |
| --- |
| Spatial Database Software Developer at AURIN |

**Q1.9.8 Staff ID** *(optional)***:**

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| --- |
| ​112002 |

**Q1.9.9 ORCID Identifier** *(optional)***:**

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| --- |
| ​0000-0002-6825-4993 |

**Q1.9.10 Position on the research project:**

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| --- |
| Associate/Assistant/Sub-/Co- Investigator/Researcher |

**Q1.9.12 Research activities Dr Hao Chen** **will be responsible for:**

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| --- |
| Dr Chen will work closely with project partners to capture requirements and deliver software tools and data assets. |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| Dr Chen is a spatial database software developer at AURIN. His expertise lies within the geographic information system and spatial information science domain, where he has worked as tutor and research assistance. Hao has obtained certificate for the “Introductory and Advanced Analysis of Linked Health Data” summer school subjects for professional development, in order to gain experience in using linked data and better work with the data. The course is taught by Professor David Preen (named investigator on this HREC application) in Nov 2022. Details on the units, including the contact dates are available at https://www.uwa.edu.au/schools/population-global-health/Seasonal-School). |

*Name:*  **Flavia Barar**

**Q1.9.4 Email Address:**

|  |
| --- |
| bararf@unimelb.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

|  |
| --- |
| No |

**Q1.9.6 Is this person a student on this project?**

|  |
| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

|  |
| --- |
| Flavia Barar is a Data Science Officer at the Australian Urban Research Infrastructure Network within The University of Melbourne |

**Q1.9.8 Staff ID** *(optional)***:**

|  |
| --- |
| ​111432 |

**Q1.9.9 ORCID Identifier** *(optional)***:**

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| --- |
| ​0000-0003-2344-2920 |

**Q1.9.10 Position on the research project:**

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| --- |
| Investigator/Researcher |

**Q1.9.12 Research activities Flavia Barar** **will be responsible for:**

|  |
| --- |
| Ms Barar will deliver spatial analysis according to the outlined methodology and develop the heat health indicator case study. |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| Ms Barar has expertise in urban analytics and community vulnerability, with international experience working as a research assistant and tutor in urban liveability, health and sustainability projects. As a Data Science Officer at AURIN she has been involved in multiple urban and spatial analysis projects. Ms Barar has obtained certificate for the “Introductory and Advanced Analysis of Linked Health Data” summer school subjects for professional development, in order to gain experience in using linked data and better work with the data. The course is taught by Professor David Preen (named investigator on this HREC application) in Nov 2022. Details on the units, including the contact dates are available at https://www.uwa.edu.au/schools/population-global-health/Seasonal-School). |

*Name:* **Dr Fadhillah Norzahari**

**Q1.9.4 Email Address:**

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| --- |
| fadhillah.norzahari@rmit.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

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| --- |
| No |

**Q1.9.6 Is this person a student on this project?**

|  |
| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

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| --- |
| Spatial Research Manager at RMIT University (124 La Trobe St, Melbourne VIC Melbourne City campus, Building 15, Level 4) |

**Q1.9.8 Staff ID** *(optional)***:**

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**Q1.9.9 ORCID Identifier** *(optional)***:**

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**Q1.9.10 Position on the research project:**

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| --- |
| Investigator/Researcher |

**Q1.9.12 Research activities Dr Fadhillah Norzahari** **will be responsible for:**

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| --- |
| Dr Norzahari will perform spatial analysis according to the outlined methodology and develop the heat health indicator case study. |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| Dr Norzahari has worked in both academia/research, and the consulting industries (engineering, strategic, and management consulting) in both Melbourne and Sydney.  Prior to joining RMIT, she was the GIS team leader at SMEC, working predominantly on major construction and infrastructure projects around Australia and internationally. She was seconded to the NSW Department of Planning & Environment to develop and implement urban and regional planning strategies for Sydney on behalf of the Greater Sydney Commission.  Her postgraduate research studies at UNSW was in remote sensing. Her dissertation was on the use of lidar for stem-classification and derivation of volume and biomass for carbon sequestration. This research was in collaboration with Forests NSW and the UNSW School of Civil & Environmental Engineering. She has also worked as a sessional academic at the UNSW Faculty of Engineering and Faculty of Built Environment. |

*Name:* **Prof David Preen**

**Q1.9.4 Email Address:**

|  |
| --- |
| david.preen@uwa.edu.au |

**Q1.9.5 Is this person the contact person for this application?**

|  |
| --- |
| No |

**Q1.9.6 Is this person a student on this project?**

|  |
| --- |
| No |

**Q1.9.7 Institutional affiliation and position:**

|  |
| --- |
| Chair in Population Health  School of Population and Global Health, The University of Western Australia |

**Q1.9.8 Staff ID** *(optional)***:**

|  |
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**Q1.9.9 ORCID Identifier** *(optional)***:**

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**Q1.9.10 Position on the research project:**

|  |
| --- |
| Associate/Assistant/Sub-/Co- Investigator/Researcher |

**Q1.9.12 Research activities Prof David Preen** **will be responsible for:**

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| --- |
| Professor Preen will advice on epidemiological approaches to the data analysis and interpretation of findings |

**Q1.9.13 Expertise relevant to the research activity:**

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| --- |
| Professor David Preen is the Chair in Public Health at the School of Population and Global Health, The University of Western Australia (UWA). He was the Director of the UWA Centre for Health Services Research from 2006-2016 and holds an honorary academic appointment at the Swansea University (UK). Prof Preen has been involved with conducting public health and health services research using whole-population linked administrative health data for over 15 years to study areas including: i) health of marginalised populations, ii) social determinants of health; iii) pharmaco-epidemiology, iv) hospital utilisation, and vi) methodological advances using data linkage.    **Contribution to the profession** Due to his expertise in linked data research, Prof Preen has been a member of >20 institutional, state and national committees including: i) the Data Linkage Australia Advisory Board; ii) Sax Institute Board; iii) NHMRC Research Committee; iv) NHMRC Australian Health Ethics Committee; v) Longitudinal Study of Australian Children (LSAC) Advisory Committee; vi) Chair; 2018 Precision Public Health Asia Conference; vi) Chair; Scientific Committee for the 2020 International Population Data Linkage Conference; vii) Chair; Cancer Council of Western Australia Research Committee; viii) National Prescribing Service MedicineInsight Data Governance Expert Committee; ix) Editorial Board of the International Journal of Population Data Science; x) Australian Health Review Editorial Advisory Committee; and xii)  NHMRC Grant Review Panels over many years.    **Supervision and mentoring** Prof Preen has supervised >45 graduate/postgraduate research students (32 as the principal supervisor). This includes 26 PhDs (21 completions) and 15 Masters (14 completions, 9 with Distinction). In addition, supported through his research grants, Prof Preen has built research capacity through direct employment and mentoring of 27 early career research staff which he has been responsible for managing and supervising since 2006.  **Example of research and/or policy impact** Prof Preen has a long history of translation of research findings to policy and practice. Some examples of translational impact from research he has led include: i) research into the impact of family and domestic violence (FDV) on children referenced in the $20M Commonwealth Government contribution toward the Domestic and Family Violence National Partnership Agreement with States and Territories, and a $6.5M investment from the NSW Government to fund specialist workers to support children and teenagers living in women’s refuges at risk of FDV; ii) evaluation of a $50M program aimed at improving wellbeing and access to services for Aboriginal people in WA resulted in more secure funding of Aboriginal health programs in WA with service performance evaluation now embedded in Aboriginal health services in WA regions; iii) establishment of routine evaluation of the use of Schedule 8 prescription medicines (ie, drugs of dependence) in WA which led to a 25% reduction in the rate of stimulant use by WA boys and a 30% reduction in GP co-prescribing of stimulant medications in the State; iv) research examining access to primary care among people released from prison led the 2018 Medicare Benefits Schedule Review Taskforce to recommend changing Medicare policy to include a subsidy for health assessments for the >63,000 prison releases in Australia annually; v) research on the combined effects of smoking and alcohol on head and neck cancers that was used as the supporting evidence by the WA Government to enable legislation to ban smoking in clubs and pubs within the State (WA was the first State in the country to implement these anti-smoking laws); and vi) research demonstrating the safety of methoxyflurane use in trauma settings for pregnant women was used in a formal submission by MundiPharma International to the US Therapeutic Goods Administration to register the medication for use in America. |

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Disclosure of interests

**Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?**

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| No |

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Restrictions

**Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?**

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| --- |
| No |

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Evaluations

**Q1.12 Has the scientific or academic merit of the research project been evaluated?**

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| --- |
| Yes |

**Q1.12.1 What was the review process and what was the outcome?**

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| --- |
| Dr Chayn Sun has completed the review recently in May 2022, and the review form has been attached below. In addition, the project also has a panel of experts to assess and provide on-going guidance and advice on the project’s scientific and technical development. Details of the panel can be found in this link: https://aurin.org.au/project-advisory-committee-for-the-australian-urban-health-indicators/. |

**Q 1.12.2 Attach evidence of the outcome of the scientific or academic review process.** *(optional)*

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| --- |
| PHSREC-PeerReviewReport\_CHEREL\_ChaynSun\_signed.docx |

**Q1.13 Has this research project had prior ethics review?**

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| --- |
| No |

**Q1.14 Will any further or additional specialised review of this application be sought?**

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| --- |
| No |

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Setting of research

**Q1.15 Will this project be conducted at multiple sites?**

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| --- |
| Yes |

**Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?**

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| --- |
| No |

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|  |

Section 2 – Research Details and Participants

Q1.17 The following research methods will be used in the research project:

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| --- | --- |
| Research Method | Status |
| Action research | ✘ |
| Biospecimen analysis research | ✘ |
| Data linkage research | ✔ |
| Ethnographic research | ✘ |
| Epidemiological research | ✔ |
| Interventional/Clinical Trials research | ✘ |
| Observational research | ✘ |
| Survey/Interview/Focus Group research | ✘ |
| Textual analysis research | ✘ |
| None of the above | ✘ |

Q1.18 The research will be conducted with the following:

|  |  |
| --- | --- |
| Participation | Status |
| Human beings (via active participation), including their associated biospecimens and/or data. | ✘ |
| Human biospecimens only | ✘ |
| Data associated with human beings only (i.e. as the primary object of research) | ✔ |

Q1.18.1 **Does your research involve the prospective collection of data?**

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| --- |
| No |

Q1.19 The research will involve the following participants:

|  |  |
| --- | --- |
| Participants | Status |
| Women who are pregnant and the human fetus | ✘ |
| Children and young people | ✘ |
| People highly dependent on medical care who may be unable to give consent | ✘ |
| People with a cognitive impairment, intellectual disability or mental illness | ✘ |
| People in dependent or unequal relationships | ✘ |
| People who may be involved in illegal activities | ✘ |
| People in other countries | ✘ |
| Aboriginal and Torres Strait Islander peoples | ✘ |

Method Specific Questions

Data Linkage Research

M3.1 How will your research/findings account for any limitations arising from your choice of data sets/databases or from missing data?

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| --- |
| Prior to undertaking the research, we will perform cross-tabulations by year for each variable in the datasets requested. This will allow us to determine the degree of missingness and if the missingness in consistent over time or if there are certain years where the data is missing.  If data are missing for specific periods of time,  we will modify the analysis accordingly or restrict analysis to periods when data are complete. |

M3.2 How will you control for confounding factors or other vulnerabilities toward bias in your research?

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| --- |
| Each heatwave period will be compared for non-heatwave periods by controllng or stratifying for demographic factors (e.g. age group, sex, socio-economic status), SA1 level geographical location, neighbourhood livability and clinical history (e.g. history of cardiovascular disease, health care utilisation). |

M3.3 How will you manage any risk that linking databases of non-identifiable data could subsequently result in the individuals being identified?

|  |
| --- |
| In protecting the privacy of individuals, the following points are also relevant to our research proposal:  (i)        All patients will be identified by a project specific identification number;  (ii)       There will be no contact with members of the study cohort;  (iii)      The research team is not involved in clinical work, therefore the risk of patient identification is very low;  (iv)      Names and addresses are not included in our datasets;  (v)       We have a highly experienced team of researchers covering various disciplines who are aware of issues of confidentiality and privacy through our numerous similar studies that have addressed these issues;  (vi)      Sensitive data will be stored within SURE and accessible only by the named investigators. Aggregated results of statistical analyses will be kept in AURIN.  (vii)     All publications and presentations arising from this project will not contain any identifying information, and no individual, medical practice or hospital will be identified or identifiable in such material.  (viii)    Upon completion of the analyses and the study, the datasets will be archived in the same network location and with the same security policy and access as was used during the study.  (ix)    The data will be used in a manner consistent with its use by Government agencies when they report on patient health outcomes. However, our team has the technical expertise for using advanced statistical methods and providing insights beyond what is available in Government reports. The results of these enhanced analyses will be published in national or international peer reviewed journals, reported at scientific conferences, and be translated into lay language, with assistance from our consumer representatives, to be disseminated through the websites of the collaborating organisations. |
|  |

Epidemiological Research

M5.1 What population/s will be studied?

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| --- |
| The cohort is population of all ages living in major urban areas in New South Wales (please see attachment titled Health Liveability Study Areas with map and list of identified areas) who presented to a NSW Emergency Department, admitted to hospital or died between 2016 and 2021, with 10 years lookback. |
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Participant Specific Questions

Recruitment Questions

As the research involves Data associated with human beings only, no recruitment questions were asked. Any issues related to access to the data and consent to its use initially in the Consent Section and Data and Privacy Section

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Consent Questions

Q2.2.5 Has consent been obtained from participant for the use of their data in the proposed research?

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| --- |
| No |

Q2.2.5.2.1 Explain why consent for use (or secondary use) of the data has not been obtained?

|  |
| --- |
| We are seeking waiver of consent for both cohorts based on the following justifications:  (i)        there is no direct involvement of patients in the research, but we will use data that were derived from their previous encounters with health service providers dating back to 2001 (depending on the data source);  (ii)       since the names or addresses of people are not included in the data extract provided to the research team, any requirement to seek consent will increase the threat to privacy due to the need to identify these people for the purpose of seeking consent;  (iii)      it is reasonable to assume that most patients would have consented to our research proposal if they had been asked;  (iv)      there will be an estimated 10,000+ patients, making it very difficult to obtain informed consent from this large number of patients, some of whom would have died while others may be in poor health as a result of their illness. Excluding patients who have died would seriously affect the scientific merit of the study;  (v)       attempts to collect consent from patients (or their carers) who have experienced adverse events could induce unnecessary anxiety or distress;  (vi)      de-identified data provided to the research team to be used in the analyses provides no potential threat to the well-being of the patients concerned because treatments have already occurred. The benefit is that we will determine geographical variations in heat vulnerability, liveability and public health outcomes;  (vii)     measures to ensure privacy and the confidentiality of information during the data linkage will follow well-established procedures developed by CHeReL. These methods are now well established as being protective of the privacy of individuals. |

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Risk Questions

**Q** **2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description** as appropriate.

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| --- |
| This study uses administrative health data and as such there is no direct contact between researchers and participants.  There is very minimal risk to patient privacy. |

**Q** **2.3.2 Describe how these risks will be mitigated and managed.**

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| In protecting the privacy of individuals, the following points are also relevant to our research proposal:  (i)        All patients will be identified by a project specific identification number;  (ii)       There will be no contact with members of the study cohort;  (iii)      The research team is not involved in clinical work, therefore the risk of patient identification is very low;  (iv)      Names and addresses are not included in our datasets;  (v)       We have a highly experienced team of researchers covering various disciplines who are aware of issues of confidentiality and privacy through our numerous similar studies that have addressed these issues;  (vi)      Sensitive data will be stored within SURE and accessible only by the named investigators. Aggregated results of statistical analyses, once approved, will be kept in AURIN.  (vii)     All publications and presentations arising from this project will not contain any identifying information, and no individual, medical practice or hospital will be identified or identifiable in such material.  (viii)    Upon completion of the analyses and the study, the datasets will be archived in the same network location and with the same security policy and access as was used during the study.  (ix)     The data will be used in a manner consistent with its use by Government agencies when they report on patient health outcomes. However, our team has the technical expertise for using advanced statistical methods and providing insights beyond what is available in Government reports. The results of these enhanced analyses will be published in national or international peer reviewed journals, reported at scientific conferences, and be translated into lay language, with assistance from our consumer representatives, to be disseminated through the websites of the collaborating organisations. |

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Benefit Questions

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your **Project Description** as appropriate.

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| The proposed research is relevant to all Australians given the risk of adverse health outcomes associated with heat waves which are becoming more frequent with climate change.  The findings are expected to lead to improved understanding of urban planning and design options for positive public health outcomes, leading to improved urban planning and decision making. The research will also contribute assets to the research community that will help other researchers investigate similar phenomena in the built environment at every stage, from data integration and analysis methodologies. |

Q2.4.2 Explain how benefits of this research justify any risks or burdens associated with the research.

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| This project will develop new indicator data assets to improve our understanding of the health of urban populations and identify incidence patterns and key risk factors across the population. We will integrate health, socio-economic, environmental, climate and built environment datasets to provide a holistic spatially-explicit understanding of urban population health. These indicators will allow health, urban and social infrastructure planners and policy makers to develop targeted policies and actions, and the outcomes will be shared with the research community. |

Q2.4.3 How will you manage participants’ expectations of the perceived benefit of participating in the research?

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| There will be no contact with members of the study cohort and hence there will not be participant expectations of perceived benefits to manage. |

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Section 3 – Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project.

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| Health information |

Q3.2 Indicate the type of information/data you will be using in this project:

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| Health information |

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.

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| Re-identifiable (coded) information |

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.

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| --- |
| Re-identifiable (coded) information |

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

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| (i)        All patients will be identified by a project specific identification number;  (ii)       There will be no contact with members of the study cohort;  (iii)      The research team is not involved in clinical work, therefore the risk of patient identification is very low;  (iv)      Names and addresses are not included in our datasets;  (v)       We have a highly experienced team of researchers covering various disciplines who are aware of issues of confidentiality and privacy through our numerous similar studies that have addressed these issues;  (vi)      Sensitive data will be stored within SURE and accessible only by the named investigators. Aggregated results of statistical analyses will be kept in AURIN.  (vii)     All publications and presentations arising from this project will not contain any identifying information, and no individual, medical practice or hospital will be identified or identifiable in such material.  (viii)    Upon completion of the analyses and the study, the datasets will be archived in the same network location and with the same security policy and access as was used during the study.  (ix)       The data will be used in a manner consistent with its use by Government agencies when they report on patient health outcomes. However, our team has the technical expertise for using advanced statistical methods and providing insights beyond what is available in Government reports. The results of these enhanced analyses will be published in national or international peer reviewed journals, reported at scientific conferences, and be translated into lay language, with assistance from our consumer representatives, to be disseminated through the websites of the collaborating organisations. |

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.

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| Publicly held database (State or local) |

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

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| We are seeking waiver of consent for both cohorts based on the following justifications:  (i)        there is no direct involvement of patients in the research, but we will use data that were derived from their previous encounters with health service providers dating back to 2001 (depending on the data source);  (ii)       since the names or addresses of people are not included in the data extract provided to the research team, any requirement to seek consent will increase the threat to privacy due to the need to identify these people for the purpose of seeking consent;  (iii)      it is reasonable to assume that most patients would have consented to our research proposal if they had been asked;  (iv)      there will be an estimated 10,000+ patients, making it very difficult to obtain informed consent from this large number of patients, some of whom would have died while others may be in poor health as a result of their illness. Excluding patients who have died would seriously affect the scientific merit of the study;  (v)       attempts to collect consent from patients (or their carers) who have experienced adverse events could induce unnecessary anxiety or distress;  (vi)      de-identified data provided to the research team to be used in the analyses provides no potential threat to the well-being of the patients concerned because treatments have already occurred. The benefit is that we will determine geographical variations in heat vulnerability, liveability and public health outcomes;  (vii)     measures to ensure privacy and the confidentiality of information during the data linkage will follow well-established procedures developed by CHeReL. These methods are now well established as being protective of the privacy of individuals. |

Q3.8 Was the information/data that you are using previously collected for a purpose other than research?

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| Yes |

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

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| The proposed research is relevant to all Australians given the risk of adverse health outcomes associated with heat waves which are becoming more frequent with climate change.  The findings will lead to understanding of the potential of different urban planning and design options for positive environmental public health outcomes.  Hence, the public interest in the study should outweigh the threat to privacy. |

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Activities Planned for/with Data

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

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| No |

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?

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| All notes, publications and presentations arising from this project will not contain any identifying information, and no individual, medical care or hospital will be identified or identifiable in such material.  Furthermore, we will suppress small cell counts (e.g. n<5) to protect confidentiality and will therefore be applied when disseminating the results of the study. |

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?

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| No |

Q3.12 Do you plan to share any individual research results obtained during this research to the participants?

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| No |

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

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| The conditions for access to linked health data do not permit analysis other than those that are outlined in the application. If we need to analyse secondary or incidental finding, we will submit an amendment to the data custodians, CHeReL and HREC or submit a new application. |

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

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| All unit record data obtained for this project will be securely destroyed 7 years after publication of the final output. This is in accordance with the NHMRC’s guidelines on data retention in their Australian code for the responsible conduct of research, which recommends a minimum of five years from the date of publication. Once the 7 years has elapsed, all original unit record data files will be deleted from the secure network and any backup drives containing those original files.  Information generated as part of this project (aggregated results of statistical analyses) will be stored indefinitely. |

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

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| Some people may be uncomfortable to know that researchers are analysing data that have been obtained without their consent. However, the datasets do not contain any identifying information like names or full dates of birth.  All research staff accessing the data have signed a confidentiality agreement. |

Q3.16 Will the outcomes of this project be disseminated to the participants?

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| No |

Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants.

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| There is no patient involvement in this project |

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

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| Information generated as part of this project (aggregated results of statistical analyses or area-based aggregated health indicators, as well as other intellectual property including algorithms) will be stored indefinitely if approved by the project advisory committee and/or the delegated expert review panel as the only data that will be held at AURIN/UOM and RMIT Australian Urban Observatory (AUO) to enable further productive and collaborative research to the registered users. All unit record data obtained for this project will be archived in SURE (the secure virtual workspaces accessible only by the approved investigators in this project for case studies) and destroyed within 7 years after publication of the final output in accordance with the NHMRC’s guidelines on data retention. |

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

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| Ethics for the study will need to be current and cover the analysis that is being proposed. If this is not the case then either an amendment to the various ethics committees and custodians will be required, or an entire new ethics application will be required. |

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Section 4 – Attachments and Declarations

Attachments

The following documents have been attached to this HREA.

Project Description/Protocol

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| See attachment 2022\_ETH00905\_v1.5 - protocol\_AusUrb-HI\_HERA\_response.docx |

Other attachments

|  |  |  |
| --- | --- | --- |
| Type | Attachment File Name | Attachment Description |
| User Submitted Documents | ​01\_Cover Letter Ethics\_AusUrb-HI Heat vulnerability.pdf | Cover Letter |
| User Submitted Documents | ​04\_NSW-Privacy-Form.doc | NSW Privacy Form |
| User Submitted Documents | ​05a\_cause-of-death-unit-record-file.xlsx | Variables list for cause-of-death-unit-record |
| User Submitted Documents | ​05b\_nsw-admitted-patient-data-coll.xlsx | Variables list for nsw-admitted-patient-data-coll |
| User Submitted Documents | ​05c\_nsw-emergency-department-data-coll.xlsx | Variables list for nsw-emergency-department-data-coll |
| User Submitted Documents | ​05d\_nsw-registry-of-births-deaths-and-marriages-death-registrations.xlsx | Variables list for nsw-registry-of-births-deaths-and-marriages-death-registrations |
| User Submitted Documents | ​06a\_2022.12 Data custodian sign off\_NSW RBDM Deaths COD URF\_2023.pdf | Data custodian approval for NSW RBDM Deaths COD URF |
| User Submitted Documents | ​06b\_RE\_ 2022.12 APDC EDDC In-Principle Support and Condition.pdf | Data custodian approval for APDC EDDC In-Principle Support and Condition |
| User Submitted Documents | ​07\_[EXT] 2022.12 Technically Feasible, Sent to the Data Custodians for review.pdf | Centre for Health Record Linkage (CHeReL) Technical Feasibility Letter |
| User Submitted Documents | review response cover letter.pdf | Cover Letter Responding to Ethics Committee Feedback |
| User Submitted Documents | study area geocode.csv | Requested Document from Feedback |
| User Submitted Documents | Justification for SA1 data.docx | Requested Document from Feedback |
| User Submitted Documents | Analysis plan.docx | Requested Document from Feedback |
|  | PHSREC-PeerReviewReport\_CHEREL\_ChaynSun\_signed.docx | Evidence of prior scientific review. |
|  |  |  |
|  | Project Registration | The output from the Project Registration |

Investigator Team Declarations

**The research team has certified that:**

* All information in this application and supporting documentation is correct and as complete as possible;
* I have read and addressed in this application the requirements of the [National Statement](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) and any other relevant guidelines;
* I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
* All relevant financial and non-financial interests of the project team have been disclosed; and
* In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student’s educational program.

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| Tracy Baylis as CPI  ☑ Certified |