

CUPL Research Application

For submission to the NSW Population & Health Services Research Ethics Committee after review and approval by Sax Institute Scientific Review Panel.

## Approved umbrella project

**Title:** The 45 and Up Study Chronic Conditions Umbrella Program Linkage (CUPL)

**REGIS Reference Number:** 2021/ETH12383

**Coordinating Principal Investigator:** Dr Martin McNamara, Research Assets Division, Sax Institute

Please enter your project title here

|  |  |
| --- | --- |
| **Title** | Click or tap here to enter text. |
| **Short Title:** | Click or tap here to enter text. |
| **Version:** | Click or tap here to enter text. |
| **Date:** | Click or tap to enter a date. |

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# Project contacts

Please list all researchers and people involved and note if they require access to the study unit record data. If data access is required, please note in ‘Site’ row: “Data access via SURE at the Sax Institute”. If no unit record access is required, please select: “N/A“. A copy of all team members’ CVs must be submitted along with the application.

Please refer to the [Guide for completing a CUPL Research Application](https://www.saxinstitute.org.au/wp-content/uploads/Guide-for-completing-a-CUPL-Research-Application.pdf) for full instructions.

## Sub-study lead researcher

|  |  |
| --- | --- |
| **Title / First name / Surname** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |
| **Site:** | Choose an item. |
| **Email:** | Click or tap here to enter text. |
| **What is this person’s role:** | Click or tap here to enter text. |
| **Access to unit record data:** | Choose an item. |

|  |  |
| --- | --- |
| **Title / First name / Surname** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |
| **Site:** | Choose an item. |
| **Email:** | Click or tap here to enter text. |
| **What is this person’s role:** | Click or tap here to enter text. |
| **Access to unit record data:** | Choose an item. |

|  |  |
| --- | --- |
| **Title / First name / Surname** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |
| **Site:** | Choose an item. |
| **Email:** | Click or tap here to enter text. |
| **What is this person’s role:** | Click or tap here to enter text. |
| **Access to unit record data:** | Choose an item. |

### About the researcher(s)

Provide a summary of skills and experience of the researcher/research team and any collaborators. Please include analytical experience, experience working with linked data, publications, current scholarships, and grants. (Max 300 words per researcher)

Click or tap here to enter text.

# About the research

Please refer to the [Guide for completing a CUPL Research Application](https://www.saxinstitute.org.au/wp-content/uploads/Guide-for-completing-a-CUPL-Research-Application.pdf) for full instructions.

### 2.1 Sub-study project overview

Please provide a lay synopsis of your project. (75 – 100 words)

Click or tap here to enter text.

### 2.2 Background and rationale

Provide an introduction to the study including a brief literature review, outline of knowledge gaps, how the sub-study will address these, and the intended contribution to the field.

Click or tap here to enter text.

### 2.3 Aims

Provide a statement of primary and secondary aims/objectives, key research questions, and/or a clearly defined hypothesis where appropriate.

Click or tap here to enter text.

# Statement of relationship to CUPL

Provide a statement of how the aims/objectives of the sub-study relate to those of the overarching program of work, including which CUPL research theme(s) this sub-study relates to. Information on CUPL research themes can be found [on our website](http://www.saxinstitute.org.au/CUPL). (Max 150 words)

Click or tap here to enter text.

# Research plan

Please refer to the [Guide for completing a CUPL Research Application](https://www.saxinstitute.org.au/wp-content/uploads/Guide-for-completing-a-CUPL-Research-Application.pdf) for full instructions on completing this section.

### 4.1 Sub-study design

Please provide information about your study design.

Click or tap here to enter text.

### Population

Please describe your cohort, specifying any inclusion and exclusion criteria.

Click or tap here to enter text.

### Sub-study data sources

Please identify data sources and time period and append the [CUPL Dataset and Variable Selection Form](https://www.saxinstitute.org.au/wp-content/uploads/CUPL-Dataset-and-Variable-Selection-Form.xlsx). All data variables must include justification. Some data sources available in CUPL have additional obligations attached to their use. These include, but are not limited to: Cause of Death data and NCIMS (see [CUPL Governance Framework](https://www.saxinstitute.org.au/wp-content/uploads/CUPL-Governance-Framework.pdf)). Data items identifying Aboriginality may require approval from the Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee . Local area geography (below SA2) will require additional review and justification.

| Data source | Yes or no | Year from e.g. Jul 2001 | Year to (e.g. Dec 2006) |
| --- | --- | --- | --- |
| The 45 and Up Study (from 2005) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| NSW Admitted Patient Data Collection (from Jul 2001; based on separation date) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| NSW Emergency Department Data Collection (from 2005) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| NSW RBDM Death Registrations (from 2006) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| Cause of Death Unit Record File (from 2006) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| NSW Central Cancer Registry (from 1996) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| NSW Mental Health Ambulatory Data Collection (from 2001) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| Notifiable Conditions Information Management System (NCIMS from 1993) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| Notifiable Conditions Information Management System – COVID Cases (from 2020) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| Medicare Benefits Schedule (MBS from Jan 2001) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |
| Pharmaceutical Benefits Scheme (PBS) includes Repatriation Pharmaceutical Benefits Scheme data (RPBS) (from 2004) | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. |

Please provide any additional information here:

Click or tap here to enter text.

### Analysis plan

Describe the study outcome measures (primary and secondary) and include information on study exposure/s, covariates, and other factors and how these are defined based on the data. Provide a statistical analysis plan outlining how the aims/objectives will be met, the statistical methods to be used, and who will be carrying out the analysis. (Min 400 words)

Click or tap here to enter text.

# Research plan summary

Please summarise the above information in the table below. Further instructions can be found in the [Guide for completing a CUPL Research Application](https://www.saxinstitute.org.au/wp-content/uploads/Guide-for-completing-a-CUPL-Research-Application.pdf).

|  |  |  |
| --- | --- | --- |
| Study factors | Brief description of study factor(s) | Data source(s) |
| Outcome(s) of interest | Click or tap here to enter text. | Click or tap here to enter text. |
| Risk factors/exposures | Click or tap here to enter text. | Click or tap here to enter text. |
| Covariates/confounders | Click or tap here to enter text. | Click or tap here to enter text. |
| Cohort of interest | Click or tap here to enter text. | Click or tap here to enter text. |
| Other (please specify) | Click or tap here to enter text. | |

# Health care performance

Does your sub-study include assessment or reporting of health care performance, for example health service design and/or health service evaluation, or variation in outcomes by health care providers or organisations? (Sub-studies related to healthcare performance may require data custodian review)

Choose an item.

If yes or maybe, please describe further (max 100 words):

Click or tap here to enter text.

# Informed consent and privacy considerations

In addition to the considerations and processes outlined in the CUPL Protocol, all researchers need to consider the extent and specifics of the linked data requested for the project being proposed, and identify particular privacy risks, stigmatisation of subgroups etc. Researchers must note the conditions of the umbrella proposal and confirm their commitment to full adherence.

**The section below is completed by the Sax Institute. No further information is required from the researcher.**

Consent and privacy considerations have been outlined in both the original (February 2022) and amended (May 2022) Chronic Conditions Umbrella Program Linkage protocol (2021/ETH12383) and related attachments, in particular: Appendix6\_CUPL\_Data Governance; Appendix7\_CUPL\_Institutional Agreement, Appendix 8 Individual Researcher Deed Poll; Appendix15\_CUPL\_NSW-Privacy-Form\_2021.11.25. These apply to all sub-studies under the umbrella.

# Record of previous ethical review for this sub-study

If this sub-study has been previously submitted to a Human Research Ethics Committee, please record the details of the ethical review here.

Choose an item.

If **yes,** please provide the following details:

|  |  |
| --- | --- |
| **Name of reviewing HREC:** | Click or tap here to enter text. |
| **HREC Reference Number:** | Click or tap here to enter text. |
| **Outcome (including any conditions)** | Click or tap here to enter text. |
| **Date of Outcome** | Click or tap to enter a date. |

# Details of funding source and relationship to funders

If this sub-study has received funding from any source, this must be detailed in this section, including the amount of funding, the name and address of the funding source/s, the relationship (if any) between the funding source/s and the researcher. If the funding or access to the data is provided by the Sax Institute or its partners as part of a grant, please state this. Note: the Sax Institute and Data Custodians have the right to reject research proposals because the funding arrangements are in conflict with their responsibilities and/or governance arrangements. Please complete one box for each funder. If there is no research funding please write N/A in the first box.

|  |  |
| --- | --- |
| Funder 1 |  |
| Contact details of funder or funders: | Click or tap here to enter text. |
| Amount funder (for each source): | Click or tap here to enter text. |
| Relationship between funder and researcher (for example grant recipient, commissioned work): | Click or tap here to enter text. |
| Duration of funding: | Click or tap here to enter text. |
| Any conditions of funding: | Click or tap here to enter text. |

|  |  |
| --- | --- |
| Funder 2 |  |
| Contact details of funder or funders: | Click or tap here to enter text. |
| Amount funder (for each source): | Click or tap here to enter text. |
| Relationship between funder and researcher (for example grant recipient, commissioned work): | Click or tap here to enter text. |
| Duration of funding: | Click or tap here to enter text. |
| Any conditions of funding: | Click or tap here to enter text. |

# Sub-study data governance

Specify the data governance arrangements for the entire data lifecycle for the study. Where applicable, include information regarding:

* Data collection: specify all site(s) where data will be collected.
* Data transfer & security: specify the processes to be used between sites and methods of encryption.
* Data access, use and disclosure: specify the processes (including the use of a remote access facility).
* Data storage: include all site(s) at which data will be stored.
* Data retention: specify the period of retention of the data following completion of the project.
* Data disposal: specify how the information will be destroyed and the methods to be used.

**The section below is completed by the Sax Institute. No further information is required from the researcher.**

The Governance Framework and processes for ensuring the highest standards of data protection and security were detailed in the PHSREC approved (May 2022) umbrella study protocol (2021ETH12383). The conditions specified in the protocol apply to all sub-studies conducted under the umbrella protocol. In particular, the site for all data access will be the Secure Unified Research Environment (SURE). Researchers will not be able to access individual unit record data outside of SURE and compulsory statistical disclosure control (SDC) techniques will be applied to all data prior to export from SURE. These procedures for access to, analysis and reporting of CUPL data under the umbrella protocol comply with Data Custodian disclosure obligations across the lifecycle of each CUPL research project and are enforced via binding legal agreements.

# Outcomes and significance

Provide a short statement in plain English which relates to your original research rationale and objectives. (Max 200 words)

Click or tap here to enter text.

# Creating impact

### 12.1 Expected research outputs and activities

List and briefly describe activities you will undertake to increase the impact of your research and support knowledge translation e.g. presentations, reports, evidence briefs, educational/training material, tools, scientific publications, meetings with decision makers, policy makers, clinicians etc. (max 200 words)

Click or tap here to enter text.

### 12.2 Expected impact

Identify proposed impact e.g. influence new or revise guidelines, inform change in policy, inform a health promotion intervention, reduce mortality, improve risk behaviour, build research capacity in non-academic sectors. Please briefly describe the translational pathway and actions e.g. presentations, reports, evidence briefs, educational/training materials, new tools, scientific publications, meetings with decision makers, policy makers, clinicians etc. (max 300 words)

Click or tap here to enter text.

### 12.3 Contribution to policy, practice or planning

Summarise how your project specifically addresses chronic condition research through policy, programs and research (max 150 words)

Click or tap here to enter text.

### 12.4 Contribution to research capacity and career development

Summarise how access to CUPL/linked data and completion of the proposed project will contribute to your career development and research capacity and expertise (max 200 words)

Click or tap here to enter text.

# References

The sub-study protocol must be properly referenced, with clear in-text citations. It does not matter what referencing style is used. Be accurate and consistent in style, format and both in-text citations and reference list.

Click or tap here to enter text.

# Summary of independent peer review feedback

Please attach copies of peer reviews obtained from two independent reviewers to your application. Reviewers should complete a [Peer Review Template](https://www.saxinstitute.org.au/wp-content/uploads/CUPL-Peer-Review-template.pdf). Reviewers should have relevant content, clinical or methodological experience. Detail any actions or amendments to the protocol and/or research team made in response to the peer reviews. If no changes, check the N/A box.

N/A

I have attached my reports

# Summary of Scientific Review Panel feedback and any conditions of approval

Please detail any actions or amendments to the proposal and/or research team as a result of feedback from the Scientific Review Panel. If no changes or conditions write N/A in the box.

Click or tap here to enter text.

# Submission checklist

Researchers to check they have included information on categories 1 to 6.

|  | Required Documents | Submitted |
| --- | --- | --- |
|  | **Cover letter**  Please list all submitted documents with date and version numbers. Cover letter must be signed by the Lead Researcher. |  |
|  | **CUPL Research Application form** All sections completed. |  |
|  | **Correspondence with other HREC(s) in Australia** (*where applicable*)  If your project is an extension or addendum to a project which already has approval from another HREC, please provide a copy of the documentation approved by the other HREC and the approval letter. If the project has undergone ethical review and approval from another HREC, please provide a copy of the Approval Letter. If this is the first submission for ethical review, mark this as N/A. |  |
|  | **Peer review reports from two senior independent reviewers**  Reviewers should complete the [CUPL Peer Review Template](https://www.saxinstitute.org.au/wp-content/uploads/CUPL-Peer-Review-template.pdf). |  |
|  | **CVs from all researchers** |  |
|  | **List of all data variables requested for this sub-study with justification** Please use the [CUPL Dataset and Variable Selection Form](https://www.saxinstitute.org.au/wp-content/uploads/CUPL-Dataset-and-Variable-Selection-Form.xlsx) and submit with your proposal. |  |
| **Documents provided by the Sax Institute** | | |
|  | **Data Linkage Flow Chart** (where applicable) | As per CUPL\* |
|  | **Data Custodian sign-off for each data collection** | As per CUPL |
|  | **Centre for Health Record Linkage (CHeReL) Technical Feasibility Letter**  For projects involving data linkage through the CHeReL only | As per CUPL |
|  | **NSW Privacy Form** | As per CUPL |
|  | **Scientific Review Panel advice summary** | Sax to provide |
|  | **All documentation relevant to the project**, such as Participant Information and Consent form(s), survey tools, and questionnaires (*where applicable*) | As per CUPL |

**\***CUPL documents were approved by PHSREC on 04/07/2022.