SaxInstitute | 45 and Up Study

Guide for completing the CUPL Research Application

This guide is intended to assist in preparing the CUPL Research Application for the Sax Institute Scientific Review Panel, and then for review by the Population Health Services Research Ethics Committee (PHSREC).

Once the sub-study research protocol has been approved by the Scientific Review Panel, the protocol will be sent to PHSREC for approval. The research questions, datasets and data variables requested cannot be changed between these steps. If access to new datasets and/or data variables is requested, it will be subject to review by both the Scientific Review Panel, and by PHSREC.

Please ensure that all the information included in the CUPL Research Application is accurate, clear and properly formatted, referenced and does not contain spelling and grammatical errors. Please also ensure that all sections are completed. If a question is not applicable to your study, please select No, or write N/A in that section. Do not rearrange the form or change the headers and contents.

A summary of CUPL research principles can be found in the CUPL Governance Framework. It should be used as context for the focus and justification of the research proposed and the use of linked data to address knowledge gaps.

Researchers are required to have their completed applications reviewed by two senior independent peer reviewers prior to submission to the Sax Institute. Reviewers should use the CUPL Peer Review Template.

Title page

- The first section (Approved umbrella project) is pre-populated by the Sax institute. Do not amend.
- The second section (Title of sub-study) must detail the full title of your research project and a short title. The data will be confirmed by the Sax Institute once the protocol has been reviewed and accepted.

1. Project contacts

- All researchers must be listed with a short summary of their roles in the project.
- Access to unit record data. If access to unit record data is required answer “Y”. Only researchers requiring access to conduct analyses of the unit record data, or to supervise the research, will receive access to unit record data within SURE
- Site: Researchers requiring unit record data access note in Site row: “Data access via SURE at the Sax Institute”. If you are not accessing the unit record data select ‘N/A’.
- Section 1.1 About the researchers: Briefly outline the qualifications and experience of each team member, with emphasis on their skills and experience to use linked data and to conduct the study, or provide clinical or epidemiological or statistical expertise.
- A copy of all team members’ CVs must be submitted along with the application.

2. About the research

- Section 2.1 should be written in plain English and be succinct.
- Section 2.2 should be referenced and written in the form of a scientific research proposal.
- Ensure that the research background and rationale justify the research aims and objectives, use of linked data and selected variables (select using the CUPL Dataset and Variable Selection Form)
- Section 2.3 aims may be presented as a series of questions or dot points. If research hypotheses are included, ensure they can be answered using CUPL.

3. Statement of relationship to CUPL

- The overarching rationale for establishment of CUPL and subsequent investigation of chronic conditions are outlined in the CUPL Governance Framework. This information may be helpful for developing your rationale.
- The 45 and Up Study provides unique data on lifestyles, attitudes, behaviours, family and personal health histories and a range of exposures that may influence the onset of chronic conditions and their outcomes.

- The response to this question should highlight the key attributes of the proposed research which will address knowledge gaps about chronic conditons (whether as independent variables, predictors, confounders, interaction variables or outcomes) its potential to inform policy or practice and utilise the unique data in CUPL.

4. Research plan

- Describe your sub-study design, including population, analyses and outcome variables.
- Sections 4.1 (Sub-Study design) and 4.4 (Analysis plan) should be different – do not cut and paste the same content into multiple sections.
- Section 4.2 must clearly define the study population – for example, all 45 and Up participants, or all 45 and Up participants who have a self reported having condition Y or have been hosptialised from XXXX-XXXX dates etc.
- Section 4.4 (Analysis plan) must include descriptions of statistical techniques. Ensure that the Analysis plan will deliver on the aims and stated outcomes of interest.
- This section should be completed in conjunction with the CUPL Dataset and Variable Selection Form) (see notes below) as the information must match.
- The CUPL Dataset and Variable Selection Form has active links to the data dictionaries for each of the CUPL datasets. Researchers must familiarise themselves with the data dictionaries in order to understand the limitations or missing variables/years etc of particular datasets. For example, MBS and PBS data do not include diagnostic variables or clinical indications.
- Once your research application is approved by ethics, any change in datasets or data variables will require a new ethics amendment.

5. Research plan summary

- This section summarises the key information from section 4 and the CUPL Dataset and Variable Selection Form.
- It must correspond exactly with no ambiguities or contradictions.

6. Health care performance

- If the analysis will identify and compare providers then details need to be included in this section. The responsible data custodian will review the application.
- Examination of health care utilisation or reporting on an association between a category of providers and an outcome or descriptor does not constitute a comparison of health care providers.
- If in doubt, seek advice from the Sax Institute.
- If not relevant select No.

7. Informed consent and privacy considerations

- Section 7 has been partially populated by the Sax institute.
- Researcher to add a statement that clearly demonstrates that any particular ethical issues relating to privacy and consent that arise for the sub-study have been considered.Your statement should conclude with a declaration that researchers will fully comply with all conditions of accessing, using and reporting on data under CUPL.
- All participants in the 45 and Up cohort have consented to participation in the study, and to the linkage of their data to other datasets.The conditions for management of privacy under CUPL are outlined in the CUPL Governance Framework.
- Only named investigators are permitted to access unit record data and all access occurs in the secure SURE environment. No unit record data may be taken out of SURE. The Sax Institute curates ingoing and outgoing files.
- Researchers should familiarise themselves with the CUPL Governance Framework. The conditions pertain to data access, analysis and reporting.
- CUPL/SURE training must be completed, once PHSREC approval has been obtained and prior to gaining access to CUPL data in SURE.

8. Record of previous ethical review for this sub-study

- If the research protocol has been previously ethically reviewed, please complete this section, otherwise select No.
- If Aboriginal ethics review is a requirement of the project, this section should be completed.

9. Details of funding source and relationship to funders

- All sources of funding for the sub-study research project should be listed.
- Funding more generally, for example salary etc, does not have to be listed.
- Funding from the Sax Institute (including in-kind funding) or from a partner organisation (for example the Heart Foundation, Cancer Council NSW) should be listed.

10. Sub-study data governance

- This section is pre-populated by the Sax institute. Do not amend.
- If your substudy has a particular data governance issue, add details. Otherwise, no further information is required from the researcher.

- See comments in relation to informed consent and privacy considerations (section 7).
- The CUPL Governance Framework provides a comprehensive approach to ensuring the highest standards of data protection and security are implemented for CUPL. It is the responsibility of all researchers to familiarise themselves with the Framework.
- Privacy preservation is essential. Note limitation of reporting small cell sizes.

11. Outcomes and significance

- This should be a short statement in plain English.
- Link the content of this section back to the original research rationale and objectives.
- You do not need to be too specific in relation to research outputs. For example, state that findings will be published or presented, not that five papers and three conference papers will be completed.

12. Creating impact

- Impact is different than outputs.
- There are four separate sections – do not simply cut and paste the same content to each section. This section focusses on the "value-add" of your research and how it can be used to contribute to change in practice, policy and thus outcomes, and how you will support the translation and impact of your research.
- Focus on the value of the outcomes in filling knowledge gaps.
- Consider and describe the translational value of the study for policy and practice.
- Consider how you will engage with patients and clinicians and the community. Novel ways of engaging with the stakeholders should be mentioned if intended.
- Describe how the skills and experience gained will enhance the careers of researchers in the study team.
- The Sax Institute may be able to help with promotion of your findings or the work you are doing. Get in contact with us if you are interested.

13. 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.

14. Summary of independent peer review feedback

- Obtain two independent reviews of the sub-study protocol from senior reviewers with relevant experience. The 45 and Up team may provide advice regarding which areas of expertise may need to be sought as part of initial feedback on the EOI. The review should be completed using the CUPL peer review template. It may be necessary to make changes to your protocol in light of feedback. If this is the case, please resubmit to final protocol to the reviewer and only submit the final strong research proposal to the Sax institute.
- Provide completed peer review forms with your application and briefly identify any changes to research plan, data and/or research team as a result of feedback in this section.

15. Summary of Scientific Review Panel feedback and any conditions of approval

- The Sax Institute Scientific Review Panel will consider the two peer review reports provided by the researcher, in conjunction with other internal review, and provide feedback to the research team.
- Briefly identify any changes to research plan, data and/or research team as a result of feedback from the Scientific Review Panel in this section.
- A copy of the Panel's report will be attached when the application is submitted by the Sax Institute to PHSREC.

16. Submission checklist

- Make sure all sections have been completed.
- Submit your CUPL Research Application form as a word doc. Do not convert to a pdf.
- Ensure all attachments are included.
- Make sure that documentation naming both inside the proposal and also on files is consistent.
- Date all versions of documents. Ethics approval is applied to the named, dated and submitted documentation so later edits will not be covered.