SaxInstitute | 45 and Up Study

CUPL Governance Framework

Principles

Research conducted under the Chronic Conditions Umbrella Program Linkage (CUPL) will be focused on the generation of new knowledge which will have an impact on knowledge translation for evidence-based policy and practice in health. CUPL will provide researchers with a means to efficiently access a range of health data for use in research in health, health policy and disease management. Research will:

- Seek to generate findings which will specifically improve disease diagnosis, treatment and management
- Generate knowledge which can be used to direct and inform policy and programs in health
- Contribute to the development of a critical mass in research capability and knowledge in the area of research focus
- Enable early-mid career researchers to develop expertise and competency in the utilisation of linked data to address gaps in disease management policy and knowledge
- Link researchers to a community of practice in linked data research and knowledge generation.

Research conducted under CUPL will specifically focus on chronic disease, including multi-morbidity and chronic on acute disease exacerbations. Research will:

- Focus on interactions between different chronic conditions in adults with multimorbidity
- Focus on interactions between chronic disease development and prognosis, and behavioural and environmental factors
- Identify modifiable risk factors and optimal interventions in policy and practice to address these
- Investigate interactions between COVID-19 and chronic conditions, including both an investigation of the impact of infectious disease on chronic conditions such as cardiovascular disease, respiratory disease and cancer, and, the development of new chronic disease as a result of COVID-19 infections
- Examine the impact of COVID-19 pandemic on overall health burden, particularly in relation to risk factor management, timely access to health care and prevention services
- Examine the impact of chronic disease and chronic disease management, including in relation to COVID-19, on mental health
- Focus on at risk groups, particularly Indigenous Australians, those who experience socioeconomic disadvantage and those with disabilities.

Research findings will be made publicly accessible to health policy makers and other practitioners and researchers in the area.

Governance

The Sax Institute has a strong commitment to the promotion and translation of research into policy and practice. The governance structures in place at the Sax Institute reflect this commitment and seek to enable the conduct of rigorous, scientifically valid and ethical research, while providing policy makers, practitioners and others with the knowledge they need and will use to improve the health of Australians.

A flow-chart outlining the data governance and approval process for CUPL sub-studies is in Figure 1. The Sax Institute is committed to best practice data governance management in its handling of all data made available to it, either via external Commonwealth and State/Territory Data Custodians, or through the 45 and Up Study. The Sax Institute is the responsible entity, both legally and ethically, for ensuring compliance with all Agreements for Data Disclosure (ADDs) with all Data Custodians, and for upholding its commitments to these Data Custodians, and to the 45 and Up Study cohort in relation to the collection, storage, use and disclosure of data. The Sax Institute has four levels of data governance:

1. Internal Sax Institute arrangements

Internal arrangements include the retention of highly experienced and skilled staff, regular training to update staff knowledge and skills, and hands-on supervision with managers and supervisors meeting regularly with staff to review practices, knowledge and if required, responses to critical incidents. Staff sign a confidentiality agreement upon employment and are inducted into the Research Assets Division on commencement.

The 45 and Up Study Chief Investigator, currently held by Dr Martin McNamara, has ultimate management and responsibility for all data governance of the CUPL.

These internal arrangements complement the stringent data protections in place with access of data occurring exclusively via the Sax Institute's secure SURE platform. More details on the SURE platform and the protections embedded are provided below.

2. External arrangements

These arrangements include:

- Institutional Agreements between the Sax Institute and researcher(s)' institution/s
- A personal Deed Poll signed by every researcher involved in sub-studies.

Both the Institutional Agreement and the Deed Poll are legally binding instruments. These agreements include specific clauses binding researchers and their employing institutions to full compliance with the Data Custodians' ADDs, confidentiality requirements, and to the data governance procedures in place at the Sax Institute.

In certain circumstances, specific schedules detailing particular conditions associated with the use of some data sets or data items must be executed as part of the Institutional Agreement. An example of such a circumstance is when Cause of Death Unit Record File (COD URF) data is used.

Institutions are required to attest to the bona fide of their researchers, and researchers must not have previously been found to have breached data disclosure requirements. Researchers and Research

Institutions must also provide clear and accurate statements about the source of funding for their Project, and their relationship with the funding source. The Sax Institute reserves the right to refuse access to CUPL where the proposed project and/or its Institutional Affiliation/s and/or its funding source or relationship violates these governance requirements or those of the Data Custodians.

The requirement for ethical approval prior to access to linked data is embedded in the Institutional Agreement. All research conducted using CUPL must be conducted in full compliance with Australian Standards for the conduct of research. The list of relevant standards is contained in the Institutional Agreement and Deed Poll.

3. Independent scientific review

The Sax Institute will be responsible for nominating research to be considered by PHSREC for ethical approval under CUPL. Research will only be nominated after it has been subject to independent scientific peer review including of its consistency with the research scope and objectives articulated in this proposal umbrella protocol. All proposed researchers will be assessed in terms of their research bona fide, experience and skills, particularly in data management, and their research proposals will be scrutinised for compliance with relevant policy and procedures, including the Five Safes Policy. This will occur prior to research being submitted for review by PHSREC. The Scientific Review Panel will review independent peer review reports provided by the research team along with their application, and will critically assess the requested data variables and time periods for each. Researchers will only receive approval to access the data variables required to address the study research objectives. The proposed use of some data sets or some variables will be notified to Data Custodians. In some circumstances, proposed sub-studies will also be reviewed by Data Custodians prior to being sent to PHSREC for review. The exact circumstances where notification and review are required will occur will be determined by the Sax Institute in consultation with Data Custodians.

The members of the Scientific Review Panel will vary according to the proposal. At a minimum a panel will include:

- Senior 45 and Up Study data / research expert(s) and CUPL Chief Investigator
- Two senior independent reviewers with relevant experience. For example, senior researchers, experts in the clinical theme, experts in the analytic methods proposed, an expert in the data proposed for the project - for example Notifiable Conditions Information Management System (NCIMS) data and NCIMS COVID data
- The responsible Data Custodian where proposed sub-studies seek to access APDC and/or EDDC and/or NSW Cancer Registry data that:
    a. involve access to personally identifying information;
    b. seek information provided as small geographical areas (smaller than SA2);
    c. relate to hospital performance, health service design and/or health service evaluation, including those relating to cancer services; and
    d. include access to unit record data relating to private facilities where private facilities, including cancer facilities, are individually identified.

The Sax Institute has an established community of research expertise, from which it can draw for this review process. The Sax Institute is particularly well positioned because of its long history of working collaboratively with an extensive network of members and partners whose expertise covers a very wide range of clinical, public health, health services and population health topics and research

methods. Details of Sax Institute partners and members can be found on the Sax Institute website: www.saxinstitute.org.au

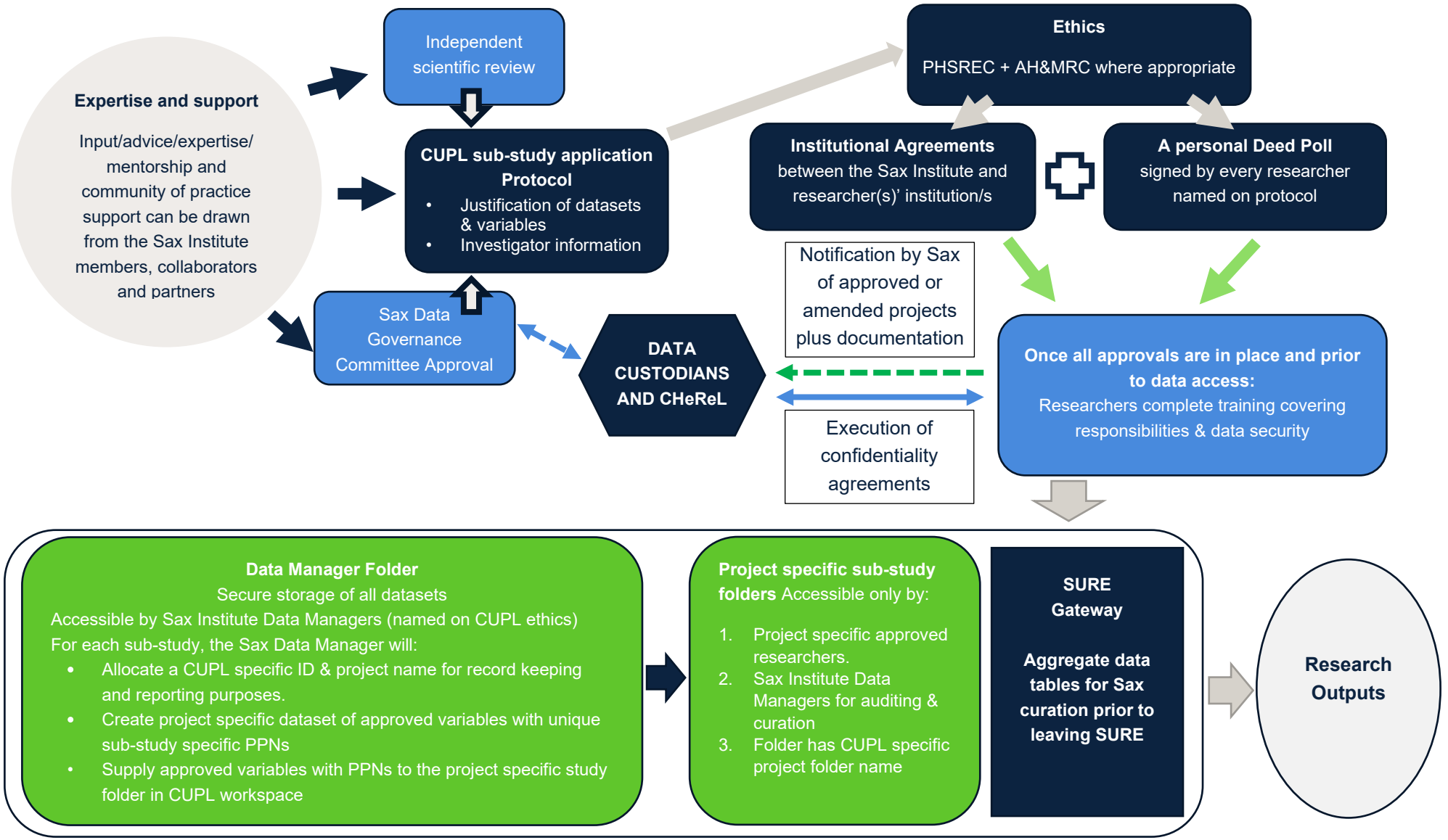
The Sax Institute will seek advice from this community as needed on proposed new research themes, and in relation to any future proposals to expand the data linkage, prior to such proposals proceeding to formal application. External advice from expert content and data management users, and from Data Custodians will be sought as required.

4. CUPL Data Governance Committee

The CUPL Data Governance Committee will be convened as the body with responsibility for overarching supervision of the data governance of the proposed CUPL at the Sax Institute, including the chronic disease research themes and sub-studies approved under the proposed CUPL protocol.

The Committee will be chaired by Emeritus Professor Michael Frommer**,** a highly experienced epidemiologist and public health expert with skills in research governance and data management. The Committee membership includes the 45 and Up Study Chief Investigator (Dr Martin McNamara), a senior data custodian from one of the linked datasets approved under CUPL, as well as the Sax Institute's Director of Research Assets (Dr Kerrin Bleicher) and Director of SURE (Matthew Gorringe). The Committee will meet at least quarterly and will be notified immediately of any issues arising from the use of data via SURE under the CUPL protocols. The Committee will ensure that research conducted under the protocols reflects best practice in use of public data for research purposes and complies with all relevant policy and procedures, and with Data Custodian ADDs. The Committee will have particular regard to the compliance of all research with the Five Safes Policy.

Figure 1: CUPL Data governance and data flow



Data Governance Context

The management of the 45 and Up Study and linked data at the Sax Institute involves many levels of scrutiny and protection. The 45 and Up Study is subject to ethical review by the University of New South Wales (UNSW) HREC, a process in place since its original approval in 2005, with annual reporting, as well as five year renewal. The UNSW HREC approval has recently been renewed and approved until 2026.

All NSW data linkages are undertaken by CHeReL, and in accordance with all CHeReL requirements and procedures.

Commonwealth Government Data Custodians and relevant ethics committees have continued to approve the use of the Medicare Benefits Scheme, Pharmaceutical Benefits Scheme data in line with consent provided by participants when they enrolled in the 45 and Up Study.

The Sax Institute is fully compliant with all Data Custodians' requirements and works closely with the CHeReL and Commonwealth and State/Territory Data Custodians in the updating of data, linkages and data access. The Data Custodian conditions for data disclosure are explicitly embedded in the CUPL protocol and in the legal agreements signed by Research Institutions and Researchers. All Projects which seek to access Cause of Death Unit Record File (COD URF) data will be bound by the additional conditions of Schedule 2 of the Institutional Agreement.

The Sax Institute also reports at least annually to all CUPL Data Custodians with details of all research projects conducted using the data, and of research publications and presentations arising from use of the data.

Publications using CUPL are required to be submitted to the Sax Institute for Technical Review in final draft form, at least 30 business days (6 weeks) prior to submission to a publisher. Copies of accepted publications and presentations must be submitted to the Sax Institute at least 21 days (3 weeks) ahead of intended release, with the Sax Institute to provide Data Custodians provided with a copy at least 14 days (2 weeks) prior to release.

The Sax Institute signs confidentiality agreements with data custodians and CHeReL. All publications and reports arising from the use of data under CUPL are reviewed by the Sax Institute prior to approval for release, and copies will be provided to Data Custodians in full compliance with their requirements.

CHeReL and Data Custodian notifications

- A copy of each approved project will be submitted to CHeReL to submit to Data Custodians for noting once approved.This includes the full approved application plus PHSREC approval and, where relevant, AH&MRC Ethics Committee approval. The same applies for each approved amendment.
- A list of all sub-studies, and details including but not limited to their status, the researchers, the researchers' sites, will be provided to CHeReL as determined between CHeReL and the Sax Institute.

- Each sub-study will report at least annually to the Sax Institute, and more frequently as required by the Data Custodians, in relation to the progress of their project and any changes to the protocol which have been approved by an ethics committee.
- Sub-studies which use certain data sets, including but not limited to, the Cause of Death Unit Record File, and the Notifiable Conditions Information Management Systems data will be subject to additional reporting and accountability requirements.

Data Flow

See Figure 2 for diagram of CUPL data flow.

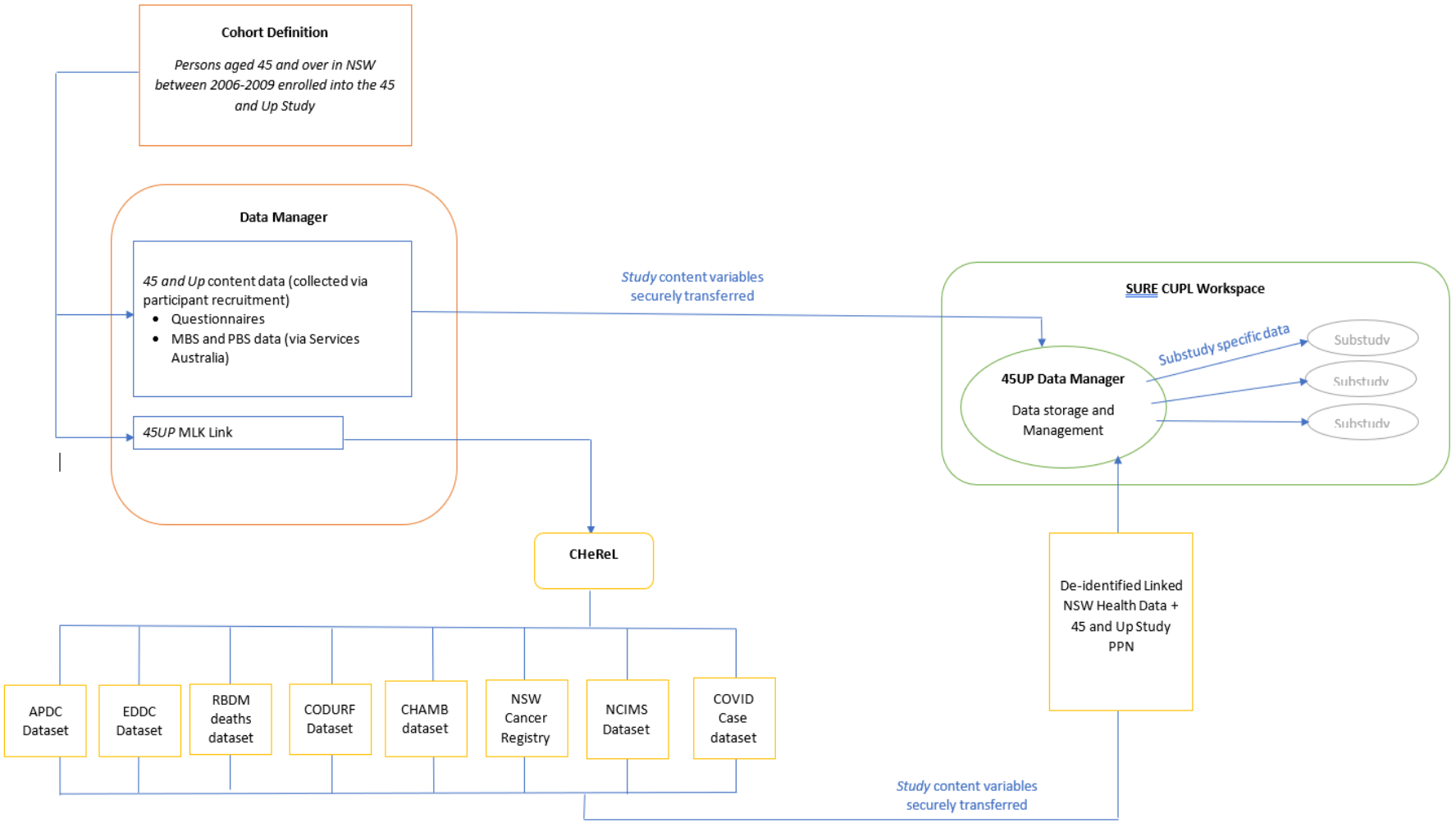
Receiving CUPL datasets

1. The data linkage facilities (e.g. CHeReL) upload the data to Secure Unified Research Environment (SURE) CUPL Workspace using new PPNs.
2. The data linkage facilities provide mapping to the new PPNs to the 45 and Up Study Data Manager.
3. The 45 and Up Study Data Manager, uploads the 45 and Up Study, MBS and PBS data to the CUPL Workspace.
4. The 45 and Up Study Data Manager curates all data and downloads it to the Data Manager Folder in CUPL Workspace.

When a sub-study is approved

1. The 45 and Up Data Manager processes the data (assigns sub-study specific PPNs to each record, selects approved variables) in CUPL Workspace (including formatting files and documentation).
2. The 45 and Up Data Manager transfers approved data into the researcher's specific Project Folder in the CUPL workspace.

Figure 2: Overarching data flow diagram



The SURE Platform, roles and responsibilities

The following SURE infrastructure and management will support the safety of the CUPL data (Figure 3). Technical details relating to SURE may be viewed at https://www.saxinstitute.org.au/our-work/sure/.

1. The Secure Unified Research Environment (SURE) provides virtual research project workspaces and individual researcher computing environments and is accessible over encrypted internet connections. A user views a facsimile of the screen of their remote virtual computer desktop on their local computer screen. The virtual computer desktops are furnished with a range of proprietary and open-source data manipulation and analysis software.
   The SURE ensures data security through secure data storage and elimination of the ability to save or download unit-record data to non-secure environments and restriction of personnel access to data. A range of information security controls relating to the access, storage and transmission of data have been built into the design of the SURE facility, including:
   a. Access to SURE requires multiple factors of authentication
   b. SURE is hosted in a tier-3+ (i.e. best available) data centre in Sydney
   c. No data is stored on a researcher's local computer or institutional computing environment
   d. Within SURE, a user cannot access the internet, email, print or copy data to a USB memory stick or other removable media. All files moving into or out of SURE pass through the Curated Gateway.
2. The CUPL Workspace is the secure space in the SURE environment which houses the data sets approved under the proposed CUPL (Figure 3).
3. The CUPL Workspace will house defined project folders established once new CUPL sub-studies are approved by PHSREC. Each 'Project Folder' will house discrete sub-studies that have been approved by PHSREC. Each project folder has a defined list of users approved to access the folder. Users cannot see or access project folders without approval and are restricted in that they can only see their own project folder, not any other project folders. The Sax Institute's CUPL Data manager can access all project folders to provide the project specific data sets without the data leaving SURE.
4. The CUPL Data Manager is a Sax employee and has access to all datasets ('Project Data File and 'defined project' subsets) within the project workspace. The CUPL Data Manager is responsible for maintaining and updating the data. The Data Manager will be responsible for provision of PHSREC approved variables to approved sub-studies. An Assistant CUPL Data Manager will provide back up for the Data Manager, ensuring that there is constant supervision.
5. The CUPL Data Manager and Assistant Data Manager are named on all ethics applications, both at the umbrella protocol level and individual Sub-study level. Study investigators named in the HREC application will only have access to the relevant defined 'Project Folder'.
6. The CUPL Data Curator(s) are Sax employee(s) responsible for reviewing, and approving or rejecting, all files moving into or out of SURE via the Curated Gateway. All files are subject to review as they pass through the Curated Gateway before they can be accessed within or outside the SURE facility. The CUPL Data Curators will also be named on the umbrella protocol and individual Sub-study ethics applications.
7. Only aggregate data will be exported from SURE. All investigators are required to apply statistical disclosure control (SDC) techniques, including but not limited to the use of aggregated cell counts

of 6 or more, to all research output from the Program to ensure privacy and confidentiality in published output. All investigators with access to data receive instruction in SDC concepts and assessment and control methods as part of the mandatory SURE user training and sign a deed outlining the terms and conditions of using SURE.

8. The Sax Institute reserves the right to audit all research arising from the proposed data linkage and conducts random audit of researcher activity within SURE, including of all files and analyses. Researchers must also make all analyses and reports available to audit by Data Custodians and/or the NSW Ministry of Health or a delegate thereof as required by the Ministry.
9. The Lead Research Organisation is responsible for ensuring that all publications and reports arising out of CUPL abide by all Conditions of Data Disclosure detailed in the Institutional Agreement, attached Schedules and Researcher Deed Poll.
10. Researchers are also required to submit all reports, publications and presentations arising from use of the data to the Sax Institute for Technical Review, at least 30 working days prior to intended submission for publication. This review will include vetting to ensure compliance with all data disclosure conditions, including those pertaining to cell size, identification of sites and facilities, and confidentiality. Researchers must also ensure compliance with specific requirements relating to particular data sets in relation to data items, source, acknowledgements and limitations of data are clearly and accurately stated. Papers which do not meet the requirements detailed in the Technical Guidelines will be returned to Researchers for amendment. Researchers agree to this, as part of the Deed Poll agreement with the Sax Institute to access any 45 and Up Study data. The Lead Research Organisation is responsible for ensuring the compliance with these conditions.
11. Researchers will submit a final copy of all publications, reports, abstracts and presentations to the Sax Institute at least 21 days prior to public release. The Sax Institute will ensure that these are made available to Data Custodians at least 14 days prior to public release.
12. Failure to comply with all conditions relating to data use, disclosure and publication may result in Researcher/s being denied future access to CUPL linked data and denied approval for publication. Serious breaches will be notified to all Data Custodians who may determine that the Researcher/s are no longer able to access the data for which Data Custodians are responsible.
13. Regular on-site and off-site backups of data are made. All off-site backups and archival data are encrypted prior to being transferred to secure off-site storage.
14. All de-identified (and potentially re-identifiable) data files will be stored in the Secure Unified Research Environment (SURE) facility, in the project's virtual workspace. Project data will be retained for at least 7 years from the cessation of the project. This time represents the likely period that interest and discussion will persist following the findings of the project. The period is in accordance with the joint NHMRC/ ARC Australian Code for the Responsible Conduct of Research (2007). Researchers must report on the disposal of files as required by Data Custodians.

Figure 3: Infrastructure for the CUPL in SURE