SaxInstitute | 45 and Up Study

A Data Access Policy

Accessing the 45 and Up Study

Cancer Council NSW

Heart Foundation

NSW

Australian Red Cross Lifeblood

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Policy Summary

The purpose of this policy is to provide guidance and instruction to manage and facilitate access to the 45 and Up Study Data. This includes principles underpinning access to Study Data, and conditions of Study Data use including ethical requirements and associated costs, processes, and responsibilities.

Enquiries regarding this report may be directed to the:

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Application

This policy applies to all individuals, researchers, staff, organisations, and institutions seeking to access or actively accessing the 45 and Up Study Data. This includes but is not limited to academic institutions, government and non-government organisations, research institutions and non-for-profits, the Sax Institute, and other organisations.

Disclaimer

This Policy may be varied, withdrawn, or replaced at any time. Compliance with this directive is mandatory for all persons, organisations accessing the 45 and Up Study Data.

Contents

Definitions

“Biobank” means the 45 and Up Study Biobank

“Biospecimens” means any human biological specimen. It includes a range of specimen types including:

- sub-cellular components such as DNA or RNA
- cells or tissues from any part of the human body
- organs
- gametes
- exhaled air
- bodily products such as teeth, hair, nail clippings, sweat, urine, faeces
- blood and blood fractions: plasma, serum, buffy coat, red blood cells
- saliva and buccal cells

“Chief Investigator” means the primary Chief Investigator on a research project as per Ethics Approval. The Chief Investigator has overall responsibility for a Project and has the authority to sign-off on instructions for SURE in relation to their project

“Core Study Data” means 45 and Up Study participant data collected by the Sax Institute via baseline and follow-up questionnaires

“Curation” means the management of data into and out of the SURE workspace

“Data” means any information relating to Study participants including but not limited to Study Data and linked health information

“Data Custodian” mean an entity responsible for the collection, ownership and/or management of a data collection or registries.

“Ethics Approval” means approval granted by a Human Research Ethics Committees (Ethics Committee) following review of the ethical acceptability of human research applications and amendments and ensuring compliance with regulatory and legislative requirements, as well as institutional policies relating to human research

“HREC” stands for Human Research Ethics Committee

“Institution” means a specifically named organisation, centre, or facility that that may access Study Data

“Licence” refers to a specific permission granted by the Sax Institute to an individual for access to Study Data, in the form of the ***45 and Up Researcher Activity Agreement.***

“Researcher(s)” means any investigator listed on the research project

“Study” means the 45 and Up Study

“Study Data” means any information about the Study participants which the Institute collects as part of the Study and provides to researchers on a conditional basis, including Core Data and data collected through Sub-studies

“Substudy” is a project that collects additional data from participants in the 45 and Up Study that is not part of the routine follow-up data collection activities

“SURE” is the Secure Unified Research Environment, a purpose-built remote-access data research laboratory operated by the Sax Institute providing a secure computing environment for analysis of Data

“Suspension” of a Workspace means the deactivation of a Workspace still maintained on SURE servers, such that it cannot be accessed by researchers without yet first being re-activated

“User” is a Researcher accessing and/or analysing Data from the Study as part of a research project

“Workspace” is a project-specific virtual interface within SURE.

Policy Overview

Purpose

The Sax Institute manages the 45 and Up Study (Study).

Researchers can apply to conduct research projects using data arising from the Study (Study Data).

The purpose of this Policy is to describe the requirements and processes to obtain approval to conduct a research project using Study Data, and the ongoing conditions for using the Study Data.

This policy outlines the principles underpinning access to Study Data, conditions of Study Data use including ethical requirements, associated costs, processes, and responsibilities.

Scope

This Policy covers all types of projects that require access to the following Study Data:

- Data from the baseline and follow-up questionnaires (Core Study Data);
- Study Data linked with data from other external data sets and collections; and/or
- Data collected from Study participants through sub-studies.

All applications to conduct a research project using data from the Study are assessed in accordance with this Policy.

A Substudy or biospecimen component of a project is defined by the Substudy Policy and Biospecimens Policy respectively.

Related Documents

Related documents including policies that may be read in conjunction with this Policy are provided in .

Table 1— Related Documents

Document Name	Document Summary	Location
45 and Up Study Fees and Charges Summary	Provides information on the costs for using the 45 and Up Study Data including Data Licence and Data Preparation costs.	***45 and Up Study Researcher Toolkit***
45 and Up Researcher Activity Agreement	This Agreement specifies contractual terms and conditions that must be satisfied and upheld by any approved projects utilising the Study Data within SURE.	***45 and Up Study Researcher Toolkit***
45 and Up Study Substudy Policy	Outlines the additional specific requirements for research projects that involve contacting and/or collecting additional data from the 45 and Up Study Participants.	***45 and Up Study Governance***
45 and Up Study Biospecimens Policy	Outlines the additional specific requirements for research projects that involve biological specimens collected by the Sax Institute from the 45 and Up Study Participants.	***45 and Up Study Governance***
SURE Access Fees Schedule	Provides a summary of standard set up and user fees.	***Using SURE***
Technical Review of 45 and Up Study papers - Guidelines for authors	Outlines requirements for referencing Study Data and other linked data within published materials including reports, manuscripts, abstracts, posters, and presentations.	***45 and Up Study Researcher Toolkit***

Requirements

Principles of Data Access

Research should be conducted responsibly, ethically and with integrity. All research projects using the Study data are expected to adhere to the following principles:

- The Study is to be used for the purposes of improving public health through research to advance knowledge.
- The Study is to be used for projects that are scientifically, methodologically, and ethically sound.
- Respect for Study participants is upheld, and their privacy protected.
- Study participants are not to be subjected to any undue burden as a result of their participation in the Study.
- The Study is a collaborative resource. Core Study Data cannot be reserved by researchers for exclusive use.
- Approval to conduct a research project using data from the Study will be assessed via a transparent process that demonstrates accountability and equity.

Conditions of Use

Provision of data is based on the following conditions:

- To access Study Data, the Sax Institute must approve a research project (refer to *Data Access Process* for application and approval processes).
- To access Linked Data from third party data providers, Data Custodian Approval must be obtained and forwarded to the 45 and Up Coordinating Centre.
- The research project and all relevant researchers must have approval from a National Health and Medical Research Council (NHMRC) registered Human Research Ethics Committees (HREC) to ensure the research proposal is ethically acceptable (Refer to *Ethics*)
- Study Data is only accessible within a SURE workspace to protect the confidentiality and privacy of research data. Additional charges apply to the use of SURE as per the ***SURE Fees Schedule***.
- An active ***45 and Up Researcher Activity Agreement***, which confers a Data Licence and SURE access, must be in place to access Study Data.
- All researchers accessing the Study data must sign a Confidentiality Agreement.
- Any public communication of findings, including media releases, scientific publications, and abstracts, conference presentations and posters, arising from the analysis of Study Data are to be submitted to the Sax Institute for Technical Review prior to submission for publication

Data Licence

A current Data Licence (Licence) for specified Core Study Data must be in place to access Study data. Each User from an organisation/institution or research group, or as an individual Researcher, are required to have a separate Licence. Licences may be purchased from the Sax Institute at a cost specified within the ***45 and Up Study Fees and Charges Summary***. The Licence for a user associated with a project will be reflected within the project's ***45 and Up Researcher Activity Agreement*** between the primary research organisation and the Sax Institute.

Each Licence holder and relevant Licence period is specified within the ***45 and Up Researcher Activity Agreement***.

Where a user is currently licensed to access Study Data for a research project under a ***45 and Up Researcher Activity Agreement*** between a Research Organisation and the Sax Institute, their Licence extends to other research projects undertaken in accordance with other ***45 and Up Researcher Activity Agreements*** between the same Research Organisation and the Sax Institute.

A higher-degree research student (Doctoral and Masters) may be covered by their supervisor's Licence, where a supervisor is a Licence holder.

Licence Period

A Licence period commences from the first date of available Data access. This is usually the date Study Data is uploaded within a project's SURE workspace, or the date the Individual user's access to the project's SURE workspace is provisioned within SURE, whichever occurs later.

Transfer of Licences

A Licence may be transferred at no cost from one user to another user within the same research institution. This transfer is subject to instruction to the 45 and Up Coordinating Centre and approval from the Chief Investigator(s) of all projects on which the original Licence holder is/was a listed Researcher.

Institutional Licences

Institutional Licence Agreements are available for academic institutions (or a faculty or research team therein) and other organisations undertaking research in line with the *Principles of Data Access*, to acquire a set number of Licences upfront. This may provide flexibility and cost savings for the organisation. Institutional Licences may be assigned to specific Users across multiple projects during the period for which the institutional Licences are valid upon written advice to the Sax Institute.

A fixed number of Discrete Service Licences are available to Study Partners listed on the Sax Institute website, as stipulated by their Partnership Agreements. Discrete Services specify a number of unallocated licences that may be assigned to Users upon written advice to the Sax Institute for any number of different research projects. Researchers wishing to access a Discrete Service Licence must be affiliated with and must apply directly to the specific Partner who will provide written advice to the Sax Institute of approval of the Licence allocation.

At the time of data supply, the following individuals must be covered by a Data Licence:

- Any investigators, including the Chief Investigator, who will access Study Data;
- All analysts or biostatisticians on the project who will access Study Data; and
- Any students who will access Study Data.

Under extreme circumstances that are outside the control of the researchers, an application to suspend the Data Licence period may be made to the 45 and Up Coordinating Centre for consideration.

Ethics

All approvals will be subject to the applicant obtaining Ethics Approval, where this is required under the *National Statement on Ethical Conduct in Human Research*.

Evidence of this approval must be provided to the 45 and Up Study Coordinating Centre before data is released to researchers. If a research project has an exemption from Ethics Approval, a letter from the relevant Ethics Committee confirming that approval is not required must be submitted to the 45 and Up Coordinating Centre (refer ***Data Access Process***).

Applications for access to 45 and Up Data that is unlinked to any other datasets or linked only to MBS and PBS by the 45 and Up Coordinating Centre, require Institutional HREC. Separate Data Custodian approval is not required for MBS and PBS Data access when this Data is linked and supplied by the 45 and Up Study Coordinating Centre.

Applications seeking to link 45 and Up Data with other state health data will require the appropriate states' Ethics Approvals for linked data. In NSW this is the NSW Population & Health Services Research Ethics Committee (PHSREC). Other specific government datasets may require governmental Ethics Approval (for example Australian Institute of Health and Welfare, Department of Veterans Affairs, etc.). This is in addition to any requisite Data Custodian approvals.

Applications for access to Aboriginal status data and/or Aboriginal Study cohort members for the purpose of conducting research with a specific Aboriginal focus must obtain Ethics Approval from the Ethics Committee of the Aboriginal Health and Medical Research Council (AH&MRC) of NSW. If there is doubt as to whether approval of the AH&MRC committee is required, please contact the AH&MRC committee secretariat.

In circumstances where a research project subsequently develops a stronger Aboriginal focus than originally proposed, the 45 and Up Study must be notified, and Ethics Approval obtained from the AH&MRC Ethics Committee.

Any variations to research protocols for research projects utilising Study Data, and any changes to the named persons accessing Study Data require an approved Ethics amendment to be submitted to the Sax Institute along with a ***45 and Up Study Research Project Amendment Form***.

Data Access Process

The Data Access Process is outlined as followed as summarised within ***Figure 1***.

Applications to conduct a research project using Study Data

Both Expression of Interests (EOIs) and Applications must be submitted using the ***Research EOI – Application Form***.

Expression of Interest and Initial Feasibility Assessment

All EOIs to conduct a research project using data from the Study will be assessed in accordance with this Policy.

Upon receipt of an EOI, the 45 and Up Coordinating Centre will perform a feasibility assessment and provide the applicant with an outcome. Where the Study Coordinating Centre has questions about the feasibility of the proposed project, they will work with the applicant to address concerns regarding feasibility.

Where an EOI is determined to be feasible, the Study Coordinating Centre will provide a letter to the applicant stating that, subject to the subsequent approval process, the proposed project is considered to be feasible. A fee estimate will also be included and may be used as supporting documentation for grant funding applications. The Feasibility Statement will note that this does not constitute approval to conduct the research project. Approval to conduct the research project will be subject to the assessment process set out below.

An indicative quote on the charges will be provided along with the Feasibility Statement.

Application and Approval Assessment

All applications to access data from the Study will be reviewed by the 45 and Up Coordinating Centre to examine whether:

- The proposed project is genuine research to be conducted in line with the Principles of Data Access
- The aim of the research is achievable using Study Data and
- The methods are broadly appropriate and applicable to the Study Data.

The 45 and Up Coordinating Centre may liaise with the applicant to resolve any queries and concerns about the application before making a decision. If the application meets the relevant requirements of this Policy and raises no ethical concerns, a project approval statement and fee estimate will be provided to the applicant for acceptance. Should the applicant wish to proceed with the proposed project, the applicant signs and returns the letter to the 45 and Up Coordinating Centre.

Where researchers have specified that they would like to have a discussion regarding their research impacts, they may be contacted by a member of the 45 and Up Coordinating Centre.

Applications to Conduct a Substudy

A Substudy is a research project that involves the active engagement and/or participation of a subset of the Study participant cohort. A Substudy may result in the collection of new and additional Study Data in the form of new participant data, which may be linked with new and/or existing health data.

The scope, requirements, procedures, and principles that underpin 45 and Up Substudies are outlined within the ***45 and Up Study Substudy Policy***.

Appeals process

The 45 and Up Coordinating Centre will endeavour to work with researchers and research organisations to facilitate the conduct of research projects using Study Data where the project aligns with the Principles of Data Access.

If a researcher or research organisation wishes to appeal the outcome of an EOI or project application, a letter of appeal can be drafted to the 45 and Up Steering Committee for consideration.

Initiation of a project using Study Data

Research Activity Agreement

Upon return of an accepted and signed letter of project approval and fee estimate, the Study Coordinating centre will prepare a ***Research Activity Agreement*** for signature by the research institution and Sax Institute. Upon execution of the agreement, an invoice for any applicable Licence, data provision and SURE access fees outlined within the agreement's schedule will be issued for payment.

SURE Access Provision

Study Data must be accessed within SURE. Following execution of the Research Activity Agreement and payment of associated fees (refer *Data Access Charges*), a SURE Workspace will be provisioned.

A Workspace may be provisioned with at least two weeks' notice to the 45 and Up Coordinating Centre, on a date nominated by the researcher.

User specific SURE access is contingent on the user having an active Study Data Licence, Ethics Approval, returned a sign SURE Deed Poll, and successfully completed of SURE training. Users will be granted access to a Workspace via a Workspace's specific Virtual Machine(s).

Data Supply

Data will be prepared and supplied within SURE. At least two weeks' notice to the 45 and Up Coordinating Centre is required. Alternatively, a later date can be nominated by the researcher.

Data supply is contingent on the payment of associated fees (refer *Data Access Charges*), and current Ethics Approvals.

Research project using linked data

It is the researcher's obligation to obtain the data custodian approval for any linked data that will be accessed as part of a research project using linked data. Approvals must be provided to the Sax Institute along with Ethics Approval before Study Data can be supplied.

Data supplied by other third-party data linkage facilities may be supplied directly by the linkage facilities to SURE.

Monitoring and ongoing use of Study Data

Monitoring

Licences, Ethics Approvals and data custodian approvals will be monitored by the Study Coordinating Centre. The Study Coordinating Centre will work with researchers to ensure Licences and approvals remain up to date. Any lapse in approvals and Licences will result in suspension of access to data within SURE.

Annual Report

The Chief Investigator of a research project accessing Study Data is required to submit an annual progress report using the ***45 and Up Annual Progress and Final Report*** form. Information supplied is used to inform our Study partners, Study participants and to update our website and other documentation.

Publications

Researchers are required to submit all papers (including abstracts for conference presentations, posters, manuscripts, and reports) for review by the study coordinating centre in line with ***Technical Review of 45 and Up Study papers - Guidelines for authors*.**

Once a submitted paper is accepted for publication and/or published, researchers are required to advise the Study Coordinating Centre.

Researchers may be contacted by the Sax Communications Team regarding their publications.

Amendments

Amendments to a project accessing Study Data including the addition or removal of researchers, requested updates to Data or addition of new Data, or amend the project's protocol require The Chief Investigator to submit a ***45 and Up Project Amendment Form***.

Submitted amendments are required to be reviewed by the Study Coordinating Centre. If the amendment is acceptable, the researcher will be notified in writing and where relevant, a fee estimate will be provided for acceptance.

Once accepted, a variation to the ***Research Activity Agreement*** will be prepared by the Study Coordinating Centre for signature by the research institution and Sax Institute. Upon execution of the agreement, an invoice for any applicable fees outlined within the varied schedule will be issued for payment.

Associated approved Ethics amendments will need to be supplied to the Study Coordinating Centre before any amendments will be applied.

Renewals

Where a project is due to be renewed, or where individual user Licences require renewal, written notification of an intent to extend should be sent to the Study Coordinating Centre. This may be done as part of an Amendment (see *Amendments*).

Conclusion of Study Data use

Closure of Project

Where a project is due to be closed, the Chief Investigator must provide written notification of an intent to close the project. All user access to the project Workspace is removed. Following the removal of user access, the Workspace may be suspended, archived, or deleted upon written instruction from the researcher, in line with data retention requirements set out within Ethics Approval.

Following closure of a project, any outstanding papers arising from analysis of Study Data are still to be reviewed by the 45 and Up Study Coordinating Centre.

Suspension

The Workspace may be suspended and maintained on the SURE servers allowing researchers with outstanding publications to access the Workspace at a later date to address questions and revisions. Limitations on suspension duration may apply.

Archive

The Workspace and all data on it can be placed on removable media and sent to a secure storage facility (archive). The workspace is subsequently deleted.

Deletion

The Workspace and all data on it can be deleted. No data is recoverable.

Continuation of SURE access without Study Data

In the event a project is due to continue, but access to Study Data is no longer required, Deletion or archive of Study Data (partial archive) is required. Upon deletion or archive of the Study Data, the Chief Investigator must provide a written and signed declaration that the Study Data has been removed to the Study Coordinating Centre.

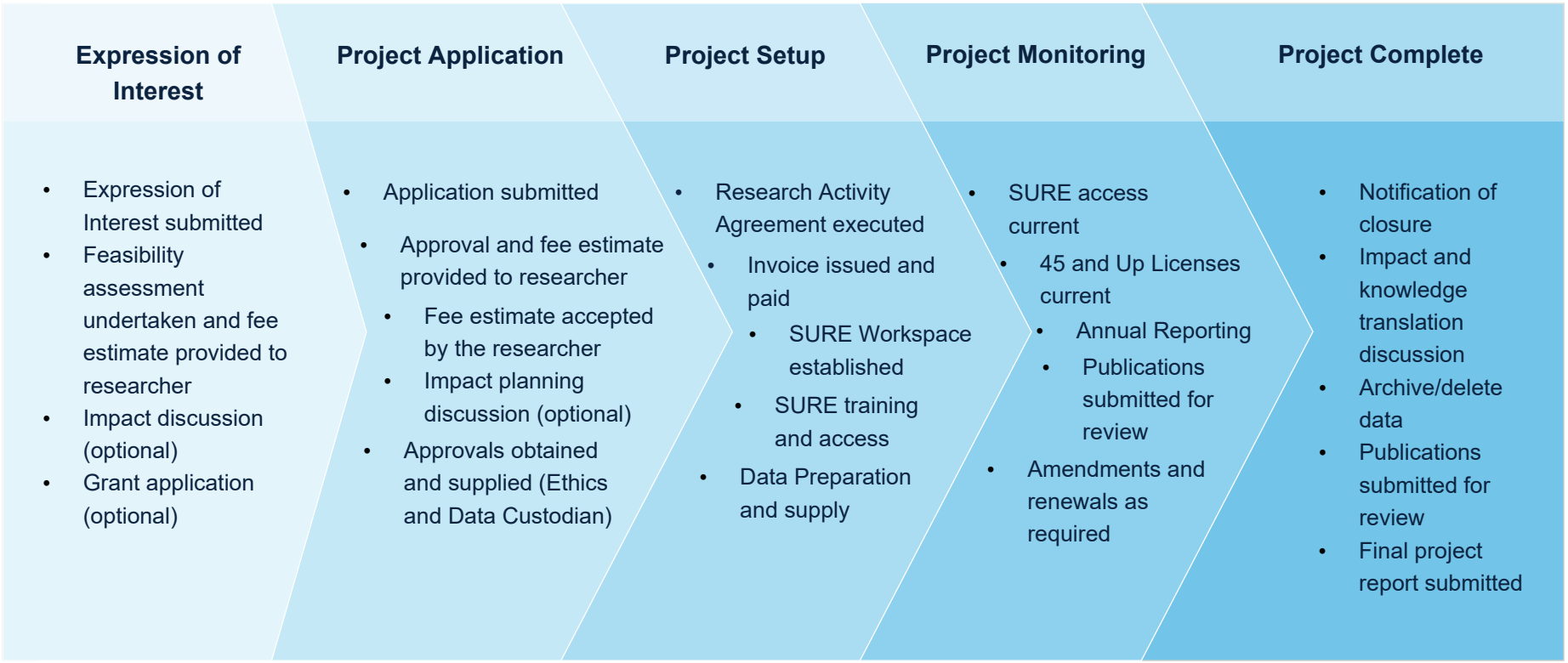
Submit final report

The Chief Investigator of a research project accessing Study Data is required to submit a final progress report using the ***45 and Up Annual Progress and Final Report*** form before or upon closure of a project.

Information supplied is used to inform our Study partners, Study participants and to update our website and other documentation

Researchers may be contacted by the 45 and Up Coordinating Centre to discuss impact and knowledge translation. Researchers may be contacted up to five years following the conclusion of a project.

Figure 1 – Data Access Process Flow



Data Access Charges

All approvals will be subject to the applicant having the requisite funding, both to conduct the project and to pay any fees and charges for use of the Study resource as set out in the ***45 and Up Study Fees and Charges Summary***.

Study Data is to be accessed only via a SURE Workspace. Additional charges apply to the use of SURE, refer to the ***SURE Fees Schedule*** available on the Sax Institute website.

Some or all fees associated with Licences and/or SURE access, including the Suspension or transfer of Licences or SURE access, and SURE Workspace establishment and maintenance may be waived under certain circumstances.