SaxInstitute | 45 and Up Study

Access Policy

Accessing the 45 and Up Study

Cancer Council NSW

Heart Foundation

NSW GOVERNMENT

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Policy Summary

The purpose of this policy is to identify the principles underpinning access to Study Data and Participants, and conditions of Study use including ethical requirements and associated costs, processes, and responsibilities.

Related documents: EOI and Application form, Fees and Charges Summary, Project Amendment Form, Author Guidelines for Technical Review, 45 and Up Study Request for Technical Review

Enquiries regarding this policy may be directed to:

45 and Up Study Coordinating Centre
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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. 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 is current as at the time of publication and may be subject to revision from time to time.

Contents

Definitions

45 and Up means the 45 and Up Study.

Biospecimens means any human biological specimen. It includes a range of specimen types such as but not limited to blood and blood fractions (e.g. plasma, serum, red blood cells), cells or tissues from any part of the human body, saliva and DNA or RNA.

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 regarding the project with the Coordinating Centre and SURE.

Coordinating Centre means the personnel at the Institute responsible for managing the 45 and Up Study and any facilities or processes required for this.

Core Study Data means 45 and Up Study Participant data collected by the Institute via baseline and follow-up questionnaires.

Data means any information relating to Study Participants including but not limited to Study Data, Linked Data and Biospecimens.

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

Deed Poll is a legally binding document setting out the Researcher's obligations.

Ethics Approval means approval granted by a human research 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.

Ethics Committee or Human Research Ethics Committee (HREC) refers to an Australian human research ethics committee registered with the National Health and Medical Research Council or an accredited body.

Exclusive Use Period is the period set out in the Research Activity Agreement for use of Sub-study Data by the Research Organisation prior to its availability for use in other research projects.

Institute refers to The Sax Institute ABN 68 095 542 886.

Licence refers to a specific permission granted by the Institute to the Research Organisation and its nominated individual(s) for access to Study Data, as defined by the Research Activity Agreement.

Linked Data means information that relates to the same individual, family, place or event from non-Study data sources (such as hospital, pharmaceutical and mortality data) that have been anonymised and may be combined with Study Data.

Participant means a person who is participating in the Study.

Research Activity Agreement refers to the agreement between the Institute and a Research Organisation to undertake a research project together with all schedules, annexures or variations to that agreement.

Research Organisation means a specifically named organisation, centre, or facility that may access Study Data.

Researcher(s) means any investigator listed on the research project, whether that Researcher will be accessing and/or analysing Data from the Study as part of the research project.

Returned Sub-study Data is Sub-study Data that has been returned by the Researchers to the Study and integrated with other Study Data; and is available for research projects.

Study means the 45 and Up Study.

Study Data means any information about the Participants that the Institute collects or derives as part of the Study and provides to researchers on a conditional basis, including Core Study Data and Returned Sub-study Data.

Sub-study is a research project that involves contacting a subset of Participants to provide additional information, test an intervention, collect biospecimens or otherwise collect additional data from Participants that is not part of the routine follow-up or other routine data collection activities undertaken by the Institute.

Sub-study Data means data collected through an approved Sub-study, including data derived from the sequencing of Biospecimens.

Sub-study Materials means any document that contains information for use in a Sub-study, including, but not limited to communication to participants such as invitations and reminders, consent forms, information statements, data collection instruments, website documents and discussion guides.

SURE or the Secure Unified Research Environment is a purpose-built remote-access data research laboratory operated by the Institute that provides a secure computing environment for analysis of Data.

Technical Review is the review of research outputs (e.g. manuscripts, reports, conference abstracts) prior to submission for publication to ensure that information as it relates to the 45 and Up Study is accurate and consistent, including that Study participants' privacy and confidentiality are protected,

User is a Researcher accessing and/or analysing Data from the Study in SURE as part of a research project.

Workspace means a virtual workspace or workspaces provided under the project's Research Activity Agreement.

Policy Overview

Purpose

The Sax Institute owns and manages the 45 and Up Study and has made undertakings to Study Participants regarding access to and use of their Data.

Researchers can apply to conduct research projects using the 45 and Up Study, including access to data arising from the Study and Sub-studies.

The purpose of this policy is to describe the principles and requirements of obtaining approval to conduct a research project using the 45 and Up Study, and the ongoing conditions for this use.

Scope

This policy covers research projects that require access to:

- Data collected by the Study in baseline and follow-up questionnaires
- Study Data linked with data from other external data sets and collections
- Data collected from Participants through Sub-studies
- Participants to conduct a Sub-study cohort research project
- Biospecimens held in the 45 and Up Study Biospecimen Collection
- Genomic data generated from analysis of Biospecimens held in the 45 and Up Study Biospecimen Collection.

All applications to conduct a research project using the Study are assessed in accordance with this policy. A Sub-study project that includes the collection of Biospecimens must meet the requirements of both this policy and any guidelines provided by the Coordinating Centre.

Requirements

Principles of Access

Research should be conducted responsibly, ethically and with integrity. All research projects using the 45 and Up Study are expected to adhere to the following principles:

- The Study is to be used for projects that are scientifically, methodologically, and ethically sound.
- Respect for Participants is upheld, and their privacy protected.
- Participants are not subjected to any undue burden as a result of their participation in the Study.
- The Study is a collaborative resource. Sub-study Data will, after the defined Exclusive Use Period, become available for use by other Researchers.

Access to the 45 and Up Study is available for use for genuine research projects with ethics approval.

Researchers and Research Organisations must clearly advise the source of funding for research projects and their relationship with that source. The Institute is a signatory to the World Health Organisation Framework Convention on Tobacco Control, which states that the Institute does not support the tobacco industry in any way. The Institute has a right to refuse to grant access to the Study where such access would violate this agreement.

Conditions of Use

The provision of Data and access to Participants for a Sub-study are based on the following conditions:

- The Institute must assess the research proposal as feasible. .
- Where required, Data Custodian approval to link data from third party data providers must be obtained and forwarded to the Coordinating Centre.
- The research project and all relevant Researchers must have approval from an Australian National Health and Medical Research Council (NHMRC) registered HREC to ensure the research proposal is ethically acceptable.
- To protect the confidentiality and privacy of research data, Study Data must only be accessed within a SURE workspace and is subject to the terms and conditions for the use of SURE.
- Payment of any applicable charges for the use of the Study and SURE.
- Sub-study Data that is collected with consent from Participants and is not linked to any other dataset may, at the discretion of the Institute, be created and analysed outside SURE. Information relating to storage, retention and access to the Sub-study Data must be included in the research project Ethics Approval.
- An active Research Activity Agreement must be in place to access the Study. This details the requirements and obligations of the Researchers and the Research Organisation; confers a Data

Licence and SURE access to accredited Researchers (if applicable); and outlines the roles and responsibilities of the parties for a Sub-study.
- Users accessing the Study must sign a Deed Poll outlining the terms and conditions of access to and use of the Study.
- Researchers involved in Sub-study projects and projects undertaken within the Chronic conditions Umbrella Program Linkage (CUPL) are required to sign a Deed Poll outlining the terms and conditions of access to and use of the Study.
- The Chief Investigator of a project must submit written reports relating to the project's progress annually and at the completion of the project, in a form and at a time specified by the Institute.
- Any proposed public communication of findings including media releases, scientific publications, reports, abstracts, conference presentations and posters arising from use of the Study are to be submitted to the Institute for Technical Review prior to submission. This is to confirm that the 45 and Up Study and other data is described and acknowledged correctly, and confidentiality requirements are met. In some cases other Data Custodians also require the proposed publication for review prior to submission. (See Author Guidelines)
- Prior to release, accepted publications must be sent to the Coordinating Centre. In some cases, other Data Custodians also require notification of the upcoming publication. (See Author Guidelines)
- Participant confidentiality must be assured, including but not limited to not publishing any results containing small cell sizes, or from which small cell sizes can be ascertained.

Ethics and Data Custodian Approvals

All research projects are subject to the applicant obtaining approvals from all relevant Data Custodians, and Ethics Approval, where this is required under the National Statement on Ethical Conduct in Human Research.

Evidence of these approvals, along with a full copy of the ethics application, must be provided to the Coordinating Centre before Study Data is released to Users. 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 Coordinating Centre.

Research projects accessing Study Data that is unlinked to any other datasets or linked only to Medicare claims data, Pharmaceutical Benefits Scheme (PBS) data, Repatriation Pharmaceutical Benefits Scheme (RPBS) data and/or Australian Immunisation Registry (AIR) data by the Coordinating Centre require institutional Ethics Approval at a minimum.

The Institute acts as Data Custodian for MBS, PBS, RPBS and AIR data of Participants when these datasets are linked and supplied by the Coordinating Centre. Approval by the Institute of a research project using these datasets includes Data Custodian approval for such use.

Research projects seeking to link Study Data with other datasets will require the appropriate Ethics Approvals for Linked Data. In NSW, this is via 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 other requisite Data Custodian approvals.

Research projects requiring access to Aboriginal status data and/or Aboriginal Participants for the purpose of conducting research with a specific Aboriginal focus must obtain Ethics Approval from the Aboriginal Health and Medical Research Council of NSW (AH&MRC) HREC. If there is any doubt as to whether approval of the AH&MRC committee is required, Researchers should contact the AH&MRC HREC secretariat.

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

All Data variables requested for the research project must be as specified in the Data Custodian approvals and included in the Ethics Approval.

Any variations to research protocols for research projects utilising the Study, and any changes to the named persons accessing Study Data, require submission of an approved ethics amendment to the Coordinating Centre with a project amendment form.

Data Access and Licences

All data Users named in the Ethics Approval, who will access Core Study Data in SURE, must hold a current data Licence for each Study dataset accessed.

The Licences for each User associated with a project and any charges for those Licences will be reflected in the project's Research Activity Agreement between the primary Research Organisation and the Institute. Any changes to Users or the Licence period must be varied in writing and relevant fees associated with the changes paid.

Licence Period

A Licence period commences from the date that the Data is first made available to the research project. This is usually the date Study Data is uploaded within a project's SURE Workspace.

An application to suspend the SURE Workspace along with the associated Data Licences can be made in writing to the Coordinating Centre. A small monthly data storage fee will be incurred.

Transfer of Licences

A Licence may be transferred from one User to another User within the same Research Organisation. This transfer is subject to written instructions to the Coordinating Centre and approval from the Chief Investigator(s) of the project on which the original Licence holder is/was a listed Researcher.

Organisation, Institutional packages, and partnerships

Organisations may wish to support the 45 and Up Study and further their research priorities through packages and partnerships. Packages and partnerships can provide flexibility and cost savings for organisations, and opportunities to collaborate with the Study in strategic areas, survey themes, grant

applications, as well as access to Sax Institute resources and support for translation of research into policy, planning and practice.

Sub-studies (New collections and interventional studies)

The 45 and Up Study actively supports and encourages Sub-studies. Sub-studies involve re-contacting participants outside of their normal follow-up schedule for a range of purposes, including to gather new information, test interventions, or collect biospecimens. The Study gives primacy to the protection of participant privacy and the reduction of undue participant burden. The Coordinating Centre can assist researchers in finding ways to minimise participant burden, develop materials consistent with the Study's existing approach to recontacting participants and increase participant response rates.

Sub-study Project Approval

Sub-study applications are considered against the following principles:

- The Sub-study is feasible.
- The research project cannot be conducted without recontacting Participants.
- The Sub-study is ethical, complies with NHMRC guidelines and receives HREC approval
- The overall burden on Participants is acceptable. Consideration of burden may include but is not limited to other projects accessing the same Participants, the length of time required to complete Sub-study tasks, the number of contacts required throughout the Sub-study and any risks that may be associated with the Sub-study.
- The Sub-study contributes to the 45 and Up Study as a collaborative resource. For example, though providing data that enriches the Study for future research
- Participant privacy and data security including data collection, transfer, storage, retention and access are assured and specified in the Sub-study ethics application.

Consideration may be given to the Researchers' experience and bona fides, the logistics of running the Sub-study, and the timing of data collection.

Further information about Sub-study applications, processes and materials can be obtained from the Coordinating Centre.

Return of Sub-study Data

All Sub-study Data collected will, after the Exclusive Use Period, become available as part of the Study Data for use by other Researchers in approved research projects. The data to be returned will include, but is not limited to, the Sub-study Data itself, a data dictionary describing the variables, any derived variables, results from analyses made on the data or Biospecimen samples, and any relevant supporting information.

Participation and Consent

Participation in all aspects of the Study is voluntary and informed consent to participate must be obtained for individual Sub-studies. The Coordinating Centre will work with researchers around their consent requirements and facilitate the process of consent for any Sub-study.

Consistent with the Study's overarching requirements, consent will be deemed not to have been given where a Participant indicates that they do not agree to one or more items on the consent form, even if the consent form has been signed. If conflicting information has been provided, the decision on whether consent has been given rests with the Coordinating Centre.

Participant information is confidential and initial contact with Participants will be made by the 45 and Up Study.

Communications and Materials

The Coordinating Centre can provide advice and assistance to support researchers in the development of participant materials to accompany Sub-studies. All materials need to be consistent with the 45 and Up Study's branding guidelines.

Sub-study Materials require approval from the Institute and an Ethics Committee prior to the commencement of Sub-study fieldwork.

The Institute reserves the right to require, within reason, that Sub-studies incorporate any Sub-study Materials and/or content it sees fit in the invitation pack or any follow up to Participants. The Institute will exercise this discretion in consultation with the Researchers and will make determinations on a case-by-case basis, giving consideration to the circumstances of individual Sub-studies.

Ethics

The Chief Investigator of the research project must seek and obtain Ethics Approval for the Sub-study, including approval for the Sub-study protocol and Sub-study Materials, and provide a copy of the full ethics application, approval and any amendments and their approvals to the Coordinating Centre.

At a minimum, it is strongly recommended that the Chief Investigator obtain in principle agreement from the Institute for a Sub-study and its Materials prior to applying for Ethics Approval.

Intellectual Property Rights

The Institute owns all intellectual property rights in Core Study Data. The Researchers own all intellectual property rights in the Sub-study Data and Sub-study Materials; and must grant the Sax Institute an irrevocable, perpetual, transferable (including the right to sub-licence), non-exclusive, and royalty free licence to use, copy and modify any data or materials that result from the Sub-study.

Access Process

Project Applications and Expressions of Interest

All expressions of interest (EOIs) and applications to conduct a Study research project will be assessed in accordance with this policy.

EOIs and applications must be submitted using the Study's EOI and application form with all relevant sections completed. This form is available on the Institute's website or by contacting the Coordinating Centre.

Feasibility Assessment

Upon receipt of an EOI or application, the Institute will perform a feasibility assessment and provide the applicant with an outcome. Where the Institute has questions about the feasibility of the proposed project, they will work with the applicant to address concerns regarding feasibility. Where a research project's EOI is determined to be feasible, the Coordinating Centre will provide a letter to the applicant stating that, subject to the subsequent approval process, the proposed project is considered feasible and acceptable under the terms of the 45 and Up Study. The feasibility statement will note that this does not constitute approval to conduct the research project.

Fee estimates

If all necessary information is included in the EOI, a fee estimate will be provided and may be used as supporting documentation for grant funding applications. Fee estimates are valid for three (3) months from the date of issue.

Applications

All applications to access the Study will be reviewed by the Institute to examine whether:

- The proposed project is genuine research to be conducted in line with the *Principles of Access* as outlined in this Access Policy.
- The research is feasible using the Study.
- The methods are broadly appropriate and applicable to the Study.

The review of applications to undertake a Sub-study will also consider:

- The availability of the desired cohort of Participants, including consideration of the project's potential to limit or prevent the conduct of other projects that would involve the same Participant group.
- The burden that may be placed on Participants joining the project.

- The desired timing and impact of the project on Study resources.
- The significance and/or anticipated scientific or policy impact of the research.

The Coordinating Centre may liaise with the applicant to resolve any queries and concerns about an application. If the application meets the relevant requirements of this policy and raises no ethical concerns, a project approval letter 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 Coordinating Centre.

Appeals Process

The Institute will endeavour to work with Researchers and Research Organisations to facilitate the conduct of research projects using the Study where the project aligns with the *Principles of Access* as outlined in this Access Policy.

If a Researcher or Research Organisation wishes to appeal the outcome of a declined research project EOI or application, a letter of appeal can be submitted to the 45 and Up Study Steering Committee for consideration by contacting 45andUp.Research@saxinstitute.org.au

Project Initiation

Research Activity Agreement

Upon receipt of a signed letter accepting the project approval and fee estimate, the Coordinating Centre will prepare a Research Activity Agreement for signature by the Research Organisation and the Sax Institute. Upon execution of the agreement, an invoice for any 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, a SURE Workspace will be provisioned.

A Workspace may be provisioned with at least two weeks' notice to the Coordinating Centre, on a date nominated by the Chief Investigator or the authorised delegate (a person nominated in writing by the Research Organisation).

User specific SURE access is contingent on the User having an active Licence, Ethics Approval, returning a signed SURE Deed Poll, and successful completion of SURE training.

Data Supply

Study Data will be prepared and supplied within the project's SURE Workspace. A minimum of two weeks' notice to the Coordinating Centre is required for the commissioning of the SURE Workspace. Alternatively, a later date can be nominated by the Chief Investigator or the authorised delegate.

Data supply is contingent on the payment of associated fees and current Ethics Approval.

Research projects using Linked Data

It is the Researchers' responsibility to obtain Data Custodian approval for any data sets required to be linked to the Study Data as part of a research project. Approvals must be provided to the Institute along with Ethics Approval before Study Data can be supplied.

Data supplied by other third-party data linkage facilities such as the NSW Centre for Health Record Linkage (CheReL) and the Australian Institute of Health and Welfare (AIHW), may be supplied directly by the linkage facilities to the project's SURE Workspace.

Sub-study Projects

Information about the roles and responsibilities of the Researchers and the Institute will be included in the Research Activity Agreement for the project. Following execution of the Research Activity Agreement by the Research Organisation and payment of associated fees, the Coordinating Centre will consult with the Researchers to develop the project, including Sub-study Materials, requirements for Ethics Approval, and the engagement of external suppliers (if required).

Researchers undertaking a Sub-study are required to protect Participants' confidential information and privacy as outlined in the Research Activity Agreement. The Institute may require a Researcher to provide a written undertaking on confidentiality and privacy.

Prior to final sample selection, the Coordinating Centre will provide the Chief Investigator with a summary document outlining the requirements for sample selection, the available sample, contact modes and timelines, for review and approval. On receipt of the signed summary document, the Coordinating Centre will undertake Sub-study fieldwork.

Ongoing Project Management

Monitoring

The Coordinating Centre will monitor Licences, Ethics Approvals and Data Custodian approvals. It is the Researchers' responsibility to ensure Licences and approvals remain up to date and to notify the Coordinating Centre of any changes. Any lapse in approvals and/or Licences shall result in suspension of access to data within SURE and/or Sub-study fieldwork.

Annual Report

The Chief Investigator of a research project accessing the 45 and Up Study is required to submit an annual progress report in a format specified by the Coordinating Centre. Reports will be requested in June and are due by 31 July each year, reflecting the project's progress to 30 June of that year. The information supplied is used to inform the Study's partners, Participants and to update the Institute's website and other documentation.

Publications

Researchers are required to submit all proposed research outputs (including abstracts or posters for conference presentations, manuscripts and reports) for Technical Review by the Coordinating Centre in line with the Study's guidelines for authors. Research outputs referencing third party data may be subject to separate requirements for review and approval by the relevant Data Custodians.

Researchers are required to advise the Coordinating Centre as soon as they become aware of the publication date of research outputs. Research projects accessing data under the Chronic conditions Umbrella Program Linkage (CUPL) must provide a copy of, or link to, the publication at least three (3) weeks prior to the publication date.

Further information about the requirements for publication is available on the Institute's website.

Amendments

Amendments to a project accessing the 45 and Up Study require submission of a project amendment form. Amendments may include the addition or removal of Researchers, updates to Data or the addition of new Data, or changes to the project's protocol, including an extension of the project's term.

The Coordinating Centre will review amendments. 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 Coordinating Centre for signature by the Research Organisation and the Institute. Upon execution of the variation, an invoice for any applicable fees outlined within the varied schedule will be issued for payment.

Associated Ethics Approval for such amendments must be supplied to the Coordinating Centre before any amendments will be applied.

Renewals

Where a project is due to be renewed, or where Licences require renewal, written notification of an intent to extend should be sent to the Coordinating Centre eight (8) weeks prior to the end date. Any extension referred to in this section will be dealt with as an amendment to the Research Activity Agreement. (See section on *Amendments above*.)

Project Completion

Closure of Project

Where a project has reached completion and is ready to be archived, the Chief Investigator must submit a completed Study Archiving Form notifying of this intent at least eight (8) weeks prior to the intended closure date.

Options available for the project's SURE Workspace at the end of a project include suspension, archiving and deletion. It is also possible to continue a project in SURE without access to Study Data.

The requirements for publications continue following closure of a project. This includes submission of any further papers arising from analysis of Study Data for Technical Review by the Coordinating Centre and any relevant Data Custodians; and advice regarding, and the provision of, accepted publications.

Access to the SURE Workspace

All User access to the project Workspace will be removed upon completion of the project. Following the removal of User access, the Workspace may be suspended, archived, or deleted upon written instruction from the Chief Investigator, in line with the data retention requirements specified in the Ethics Approval.

Suspension

An option to suspend a Workspace to allow Users with outstanding publications to re-access the Workspace at a later date to address questions and revisions is available. As the suspension of the Workspace and reinstating access requires some maintenance and storage space, a suspension fee applies. This can be pro-rated to the period required, with a minimum of one-month suspension. Users may have up to four (4) weeks free access per Workspace during a suspension for publication purposes. Amendment requests to access a suspended Workspace should be submitted via email, with a minimum of five (5) business days' notice, noting the dates and Users requiring short-term access.

Archive

Upon project completion and subject to the payment of a one-off fee, the Workspace and all data on it is placed on removable media and sent to a secure storage facility (archive). This process and the ongoing maintenance of archived information is managed by the Institute. The Workspace is subsequently deleted. Researchers should contact the Coordinating Centre if access to archived data is required. Standard 45 and Up licencing charges and costs associated with opening and maintaining a new Workspace will apply to re-access archived data.

Deletion

The Workspace and all data on it are deleted. No data is recoverable. This process is managed by the Institute.

Continuation of SURE access without Study Data

In the event a project is to continue, but access to Study Data is no longer required, deletion or archive of Study Data (partial archive) is required. This process is managed by the Institute. Upon deletion or archive of the Study Data, the Coordinating Centre will provide the Chief Investigator with confirmation of the deletion or archive.

Final report

The Chief Investigator of a research project accessing the Study is required to submit a final progress report before closure or within no more than three (3) months of project completion using a format as specified by the Coordinating Centre.

The information supplied is used to inform the Study's partners, Participants and to update the Institute's website and other documentation.

The Coordinating Centre may contact Researchers to discuss impact and knowledge translation for up to five (5) years following the conclusion of a project.

Fees and Charges

All approvals are subject to the Researchers having the requisite funding, both to conduct the project and to pay any fees and charges for use of the Study, as set out in the 45 and Up Study data fees guide on the Institute's website.

Study Data is to be accessed only via a SURE Workspace. Additional charges apply for the use of SURE.

Some or all fees associated with Licences and/or SURE access, including the suspension or transfer of Licences or SURE access, and SURE Workspace maintenance may be waived at the Institute's discretion.

Fees for Sub-study projects are determined on a case-by-case basis and vary depending on the size of the required cohort, the complexity of the project, the number of contacts with Participants, and the resources required for the project.