

THE 45 AND UP STUDY ACCESS POLICY

1. Purpose and application

- 1.1 The Sax Institute manages the 45 and Up Study (the Study). Researchers can apply to conduct research projects using data from the Study, provided the requirements of this policy are met. These research projects are projects that use:
- Data from baseline questionnaires;
 - Study questionnaire data linked with data from other external datasets; and/or
 - Data collected from Study participants through sub-studies.
- 1.2 The purpose of this policy is to describe the conditions for gaining approval to conduct a research project using data from the Study.
- 1.3 This policy does not apply to access to biological samples, as these do not yet formally constitute part of the Study resource. Conditions for access to biological samples will be included in a later version of this policy.
- 1.4 This policy should be read in conjunction with:
- a) the 45 and Up Study Fees and Charges Policy that outlines fees and charges for access to, and use of, the Study data. These fees and charges are intended to ensure the long-term sustainability of the Study and the Institute's continuing work for the public good; and
 - b) the 45 and Up Study Conditions of Use Agreement, which specifies the conditions that must be satisfied by approved users of the Study data.

2. Principles

- 2.1 This Policy is based on the following principles:
- The 45 and Up Study is to be used for the purposes of furthering the public good in relation to health.
 - The 45 and Up Study is a collaborative resource. Data elements cannot be reserved by researchers for exclusive use.
 - The 45 and Up Study is to be used for projects which are scientifically, methodologically and ethically sound.
 - The privacy of Study participants is to be protected.
 - Study participants are not to be subjected to any undue burden as a result of their participation in the Study.
 - Approval to conduct a research project using data from the Study is to be granted through a transparent process which demonstrates accountability and equity.

3. Applications to conduct a project using data from the 45 and Up Study

- 3.1 All applications to conduct a research project using data from the Study will be assessed in accordance with this policy.
- 3.2 In the first instance, the 45 and Up Study Coordinating Centre will undertake a short review of all applications to ensure that the access sought under the application is feasible and would be able to be provided if the application is approved. 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.
- 3.3 Where the application is feasible, and is for a project that is to be forwarded to a peer reviewed funding agency, the Study Coordinating Centre may provide a letter to the applicant (Stage 1 Endorsement) stating that, subject to the subsequent approval process, there are no feasibility obstacles to access being provided in relation to the application. The letter of Stage 1 Endorsement will note that this does not constitute approval to conduct the research project. Approval to conduct the research project will be subject to the approval process set out below (Stage 2 Approval).

Applications for Stage 2 (final) Approval to use baseline questionnaire data only

- 3.4 Applications for access to baseline questionnaire data will be reviewed by an independent expert to examine whether:
- a) the applicants have appropriate skills and capacity;
 - b) the aim of the research is achievable; and
 - c) the methods are broadly appropriate.
- 3.5 The 45 and Up Study Coordinating Centre will consider the recommendations made by the independent expert and either:
- Recommend approval of the application to the Chief Executive Officer of the Sax Institute (or their delegate); or
 - Recommend that the application be referred to the Study Access Committee.

Where an applicant is a staff member of the Sax Institute, the application will automatically be referred to the Study Access Committee for recommendation. Review of applications made by staff members will be undertaken by the Access Committee without need for review by an independent expert, unless the Access Committee requests additional input or expertise.

- 3.6 A recommendation that the application be referred to the Study Access Committee will occur where the 45 and Up Study Coordinating Centre determines the project raises issues as to:
- Scientific quality; or
 - Public good

The Study Access Committee will be asked to provide advice on these issues. The advice of the Study Access Committee is not binding on the 45 and Up Study, but will be significant in making a final determination as to whether Stage 2 (final) Approval is granted.

Applications for Stage 2 (final) Approval to use linked data

- 3.7 Where the project intends to use 45 and Up Study data linked with another dataset and has already been subject to scientific peer review, no further scientific review of the project will be undertaken. The 45 and Up Study Coordinating Centre will examine the scientific review to confirm that the project is scientifically valid.
- 3.8 Where the project has not been subject to scientific peer review, the application will be referred for external scientific review to examine whether:
- a) the applicants have appropriate skills and capacity;
 - b) the aim of the research is achievable; and
 - c) the methods are broadly appropriate.
- 3.9 The 45 and Up Study Coordinating Centre will consider the recommendations made by external scientific review and either:
- Recommend approval of the application to the Chief Executive Officer of the Sax Institute (or their delegate); or
 - Recommend that the application be referred to the Study Access Committee.

Where an applicant is a staff member of the Sax Institute, the application will be automatically referred to the Study Access Committee for recommendation. Review of applications made by staff members will be undertaken by the Access Committee without need for peer review, unless the Access Committee requests additional input or expertise.

- 3.10 A recommendation that the application be referred to the Study Access Committee will occur where the 45 and Up Study Coordinating Centre determines the project raises issues as to:
- Scientific quality; or
 - Public good.

The Study Access Committee will be asked to provide advice on these issues. The advice of the Study Access Committee is not binding on the 45 and Up Study, but will be significant in making a final determination as to whether Stage 2 (final) Approval is granted.

Applications for Stage 2 (final) Approval to undertake sub-studies

- 3.11 All applications to undertake sub-studies must be reviewed by the Study Access Committee.
- 3.12 In considering approval for access to the Study data for sub-studies the Study Access Committee will consider the following:
- (a) Scientific validity. Where the project has already been subject to scientific peer review, no further scientific review of the project will be undertaken. Where the project has not been subject to scientific peer review, the project will be referred for external scientific review prior to it being considered by the Study Access Committee. The Committee will then examine the scientific review to confirm that the project is scientifically valid. Where external reviews are divided on the scientific validity of the application, the Committee will resolve this issue having regard to their own expertise, or to the expertise of other appropriately qualified individuals whom they may contact for this purpose.
 - (b) Exhaustion of the Study resource. A principle of the 45 and Up Study is that access to the Study data is to be granted through a transparent process which demonstrates accountability and equity. Some projects using the Study have the potential to limit or prevent the conduct of other projects that would involve the same participant group. The Study Access Committee will assess the potential for such exhaustion, in light of other projects that may already be accessing the participants in question. The Study Access Committee may recommend against approval, or make approval conditional on changes to the design of the project, where the potential for exhaustion of the study resource is considered unreasonable.
 - (c) Burden on Study participants. A principle of the 45 and Up Study is that participants will not be subject to undue burden as a result of their participation in the Study. The Study Access Committee will consider the burden that may be placed on participants as a result of the application and may recommend against approval where the burden placed on the participants is considered unreasonable, either by the Study itself, or in light of other sub-studies accessing the same participants. Specific considerations for evaluating participant burden in sub-studies is outlined in the *Study Policy on Sub-Studies*.
 - (d) Public good considerations. A principle of the 45 and Up Study is that the Study is to be used for the public good. The Study Access Committee will consider the rationale of the application and how it contributes to the public good.
- 3.13 Following the considerations at 3.12, the Study Access Committee will make a recommendation regarding access to the Chief Executive Officer of the Sax Institute (or their delegate) for approval or non-approval of the application.

- 3.14 If the Study Access Committee recommends approval, but the Chief Executive Officer does not approve the application, the applicant will have a right of appeal to the Sax Institute Board, or a sub-committee of the Board, as determined by the Chair of the Board.

4. Ethical approval

- 4.1 All approvals will be subject to the applicant obtaining ethical approval, where this is required under the *National Statement on Ethical Conduct in Human Research*. Evidence of this approval must be provided before data are released to researchers. A letter from the relevant Ethics Committee confirming that ethics approval is not needed will be required from applicants seeking data without an ethics clearance. Please note the 45 and Up Study requires that certain wording must be included in sub-study materials, and this should be obtained by the applicant prior to seeking ethical approval.
- 4.2 For some applications, approval of the Human Research Ethics Committee of the Aboriginal Health and Medical Research Council is also required (see 6 below).

5. Data access charges

- 5.1 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 *Study Fees and Charges Policy*.

6. Access to Aboriginal status data and/or Aboriginal Study cohort members

- 6.1 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 ethical approval from the Ethics Committee of the Aboriginal Health and Medical Research Council (AH&MRC) of NSW. If there is doubt as to whether or not approval of this Committee is required, please contact the Committee secretariat.
- 6.2 Applications for access to Aboriginal status as one of an array of socio-demographic variables must undertake to ensure feedback of findings to Aboriginal communities. Applicants will be required to sign an agreement that regulates the use of the Aboriginal data when the proposal does not have an Aboriginal focus. In circumstances where a research project subsequently develops a stronger Aboriginal focus than originally proposed, the 45 and Up Study must be notified and ethical approval obtained from the AH&MRC's Ethics Committee.