THE 45 AND UP STUDY POLICY ON SUB-STUDIES

1. Purpose and application

1.1 The purpose of this policy is to outline the requirements for sub-studies of the 45 and Up Study.

1.2 Sub-studies are projects that collect additional data from participants in the 45 and Up Study that is not part of follow-up or other activity of the Coordinating Centre.

1.3 All sub-studies are required to comply with the *Australian Code for the Responsible Conduct of Research* and the *National Statement on Ethical Conduct in Human Research*. This policy should be read in conjunction with these documents.

1.4 This policy does not apply to access to projects that involve the collection of biological samples. Conditions for sub-studies involving collection of biological samples will be included in a separate policy.

1.5 This policy should be read in conjunction with the:

a) 45 and Up Study *Data Access Policy* that outlines conditions for access to the Study resource, and;

b) the 45 and Up Study *Fees and Charges Policy* that outlines fees and charges for use of the Study resource, and;

c) the 45 and Up Study *Sub-Study Agreement*, which specifies the conditions that must be satisfied by approved users of the Study resource.

2. Principles

2.1 This policy is based on the following principles:

- The 45 and Up Study relies on the ongoing goodwill of participants to continue to have their health followed over time. To maintain this goodwill, it is essential that the 45 and Up Study ensures all communications with participants meet the highest ethical, scientific and quality standards.
- 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.
- Sub-studies are to be conducted as part of the 45 and Up Study, and as such, must follow the branding guidelines for the Study.
- The 45 and Up Study is a collaborative resource. All data collected as part of the 45 and Up Study, including data collected by sub-studies, will, after a defined period of exclusive use, become available for use by other researchers in approved research projects.
- The contribution of funding partners of the 45 and Up Study, and the managing partner, the Sax Institute, must be appropriately acknowledged in all material related to the Study.

3. Participation in sub-studies

3.1 Participation in sub-studies is voluntary. Informed consent to participate must be obtained for each sub-study.

3.2 Participant information is confidential. Invitations to participate in sub-studies will be forwarded by the Coordinating Centre. The names and contact details of 45 and Up Study participants will not be released to a third party without the participants' informed consent.

3.3 Individuals may choose not to take part in a sub-study, or withdraw from a sub-study, and this will not impact on their continuing participation in the 45 and Up Study.

4. Participant burden

4.1 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.

4.2 In review of applications to undertake a sub-study, the Data Access Committee will consider the burden that may be placed on participants.

4.3 Except in special circumstances approved by the Data Access Committee, the total amount of time that participants are requested to spend on contributing data to the 45 and Up Study should not exceed four hours annually, and up to a maximum of 2 contacts annually. Calculation of participant burden will exclude administrative contacts such as the annual newsletter and verification of contact details.

4.4 Except in special circumstances approved by the Data Access Committee, the maximum amount of time that participants are requested to spend on contributing data to a specific sub-study of the 45 and Up Study is 2 hours annually.

4.5 Circumstances in which the Data Access Committee may give consideration in the determination of whether a sub-study should be approved to exceed the contact limitations specified at paragraphs 4.3 and 4.4 include, but are not limited to:

a) any written justifications provided to the Data Access Committee by the researchers for exceeding the contact limitations.

b) the significance and/or anticipated scientific or policy impact of the research.

c) time constraints, whether these are imposed by:

- the scientific methods proposed by the researchers; or
- funding agencies; or
- the need to inform policy; or
- any other source the Data Access Committee considers relevant.

5. Sub-study materials

5.1 All sub-study materials must be approved by the Coordinating Centre.

5.2 The Coordinating Centre reserves the right to require that sub-studies include any materials and/or content it sees fit, within reason, in the invitation pack to Study participants. The Coordinating Centre 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.

5.3 The Coordinating Centre, at a minimum, requires sub-studies to include the standard sub-study materials listed at the Attachment, unless otherwise expressly agreed.

5.4 The contribution of funding partners of the 45 and Up Study, and the managing partner, the Sax Institute, must be appropriately acknowledged in sub-study materials (Attachment).

6. Sub-study data and materials

Information collected through questionnaires, direct contact, interviews and measurements (e.g. blood pressure, height and weight)

6.1 Researcher(s) undertaking a sub-study will be encouraged to share the data they collect through a sub-study and the materials of the sub-study as soon as is practicable after collecting the data.

6.2 In the event that researcher(s) undertaking a sub-study are unable or unwilling to share the data immediately after collection they will have exclusive access to the data collected through the sub-study and the materials of the sub-study for a period of two years after the conclusion of data collection.

6.3 After the period of exclusive access, the researcher(s) must give the Sax Institute a copy of the sub-study data and materials.

6.4 Other researchers may wish to use sub-study data and/or materials within the period of exclusive access. In these cases, the other researchers would need to negotiate directly with the researcher(s) for specific (usually collaborative) access.

6.5 After the period of exclusive access the Sax Institute may use the sub-study data and materials and permit third parties to use these for projects approved in accordance with the *Data Access Policy*.

6.6 For a period of 5 years following the conclusion of a sub-study, the Sax Institute will notify the researcher(s) of any permission to use the sub-study data and/or materials.

6.7 Individuals or groups using sub-study data and/or materials must acknowledge the researchers for their collection and development.

7. Intellectual property rights

7.1 Intellectual property rights means all intellectual and industrial property rights and interests throughout the world, whether registered or unregistered, including trade marks, designs, patents, inventions, semi-conductor, circuit layouts and other eligible layouts, copyright and analogous rights, trade secrets, processes, concepts, plant breeder's rights, confidential information and know-how.

7.2 The Sax Institute owns all Intellectual Property Rights in data collected by the Coordinating Centre.

7.3 The researcher(s) own all Intellectual Property Rights in the data and materials collected by the sub-study; and must grant the Sax Institute an irrevocable, transferable, non-exclusive, sub-licensable and royalty free licence to use, copy and modify any data or materials that result from the sub-study.

Attachment
Items to be included in sub-study materials and positioning of acknowledgements and branding

This document outlines the general requirements for sub-study materials, in line with the 45 and Up Study *Policy on Sub-Studies*. Unless expressly agreed, all sub-studies must comply with these general requirements. Exceptions will be considered on a case by case basis.

1. Logos and Branding

As a general principle:

- all materials from the Coordinating Centre must contain the logos of the 45 and Up Study, the Sax Institute and the 45 and Up Study's funding partners
- materials specific to the sub-study should contain the 45 and Up logo and branding agreed by the researcher(s), this could be one sub-study logo or several logos to represent the organisations of each researcher involved in the sub-study

2. Invitation letter from the 45 and Up Study

- All Sub-Studies must include an invitation letter from the 45 and Up Study. The invitation letter will be provided to the researchers by the 45 and Up Study.
- The invitation letter will be one A4 page and on 45 and Up Study letterhead. The 45 and Up Study letterhead includes the logos of the 45 and Up Study, the Sax Institute and the 45 and Up Study's funding partners.
- If the invitation pack is to be mailed to potential participants, the 45 and Up Study invitation letter must be printed in full colour.
- The 45 and Up Study invitation letter may include the following information:
  - The date of the participant's enrolment in the 45 and Up Study.
  - A brief description of the 45 and Up Study
  - An explanation of the concept of a sub-study
  - A statement regarding the confidentiality of the participant's information
  - An explanation that the participant's contact details will only be given to the researchers if the participant consents to participate in the sub-study.
  - Contact details for the 45 and Up Study

3. Invitation letter from the researcher(s)

- All Sub-Studies must include an invitation letter from the researcher(s).
- The invitation letter must be no more than one A4 page and should include the logo of the sub-study and/or the researchers' institution(s).
- If the invitation pack is to be mailed to potential participants, the invitation letter from the researcher(s) should be printed on the back of the invitation letter from the 45 and Up Study.

- The invitation letter should include the following information:
  - A brief description of the sub-study
  - The following statement: *'Participation in this sub-study is entirely voluntary, and you may choose to decline this invitation and still remain in the 45 and Up Study'*.
  - A phone number potential participants can call for more information
  - The name and signature of the Chief Investigator

4. Participant information leaflet

- All Sub-Studies must include a participant information leaflet.
- The leaflet must include the logo of the 45 and Up Study and logo(s) of the sub-study and/or researchers' institution(s) at the beginning of the document and should be titled: *'Information for Participants: [sub-study name]'*. The logo of the Sax Institute and the logos of the 45 and Up Study funding partners should be included at the end of the document, with acknowledgements (as below):

- The leaflet should include the following information:
  - A description of the sub-study and its aims.
  - Why the potential participant was selected. If the sample is random, this should be stated.
  - What participation in the sub-study will involve.
  - How the information and/or Biological Specimens collected will be used by the researchers.
  - A statement as to how the researchers will maintain the confidentiality and security of the information and/or Biological Specimens collected. This should include the following statement: *'All information provided to the 45 and Up Study is bound by Commonwealth and State privacy legislation and guidelines, including the Health Records and Information Privacy Act and the NSW Health Privacy Manual. The 45 and Up Study is committed to providing a high standard in handling personal information. Your information will only ever be used for health research. The researchers conducting this sub-study will not have access to your identifying information unless you give your consent to participate'.*
  - How the potential participant can decline the invitation
  - How the potential participant can accept the invitation
  - How the potential participant can withdraw if they choose to take part. The following statement will be sufficient: *'Your participation in this sub-study is completely voluntary. If you do choose to take part, you may withdraw at any time by calling the 45 and Up Study Helpline on 1300 45 11 45. You may withdraw from this sub-study and still remain in the 45 and Up Study'.*
  - The name of the HREC overseeing the conduct of the sub-study
  - A phone number, mailing address and email address potential participants can contact for further information about the sub-study.

5. Consent form

- All Sub-Studies must include a consent form and ideally this should be part of the questionnaire. The consent that must be obtained by the researcher(s) is two-fold:
  - Consent for the 45 and Up Study to provide the researcher(s) with the potential participant's identifying information.
  - Consent to participate in the sub-study
- To satisfy consent researchers should include the following terms in the sub-study consent form:

  'I agree to the 45 and Up Study providing the researchers responsible for [sub-study name] with my identifying information (including, but not limited to: name, date of birth and address). I give my consent on the understanding that: 1. my information will only be used for the purposes outlined in the leaflet entitled 'Information for Participants: [sub-study name]', of which I have a copy; 2. my information will be kept strictly confidential and will be used for health research

only; and 3. reports and publications from [sub-study name] will be based on de-identified information and will not identify any individual taking part'.

- The consent form should include the logo of the 45 and Up Study at the beginning of the document and the logo(s) of the sub-study and/or researchers' institution(s) at the end of the document.

6. Sub-study questionnaires

- All questionnaires used in sub-studies, whether paper or web based, should include the logo of the 45 and Up Study and logo(s) of the sub-study and/or researchers' institution(s).
- To assist with readability, there is a preferred format for questionnaires being used as part of a sub-study, this includes background colour, which will be specified by the coordinating centre to ensure easy distinction between sub-studies that may be occurring at the same time.

7. Participant contact details update

- The follow-up nature of the 45 and Up Study necessitates that participants are asked to provide updated contact details at every communication; including sub-study invitations. A request to update contact details should be included in the sub-study questionnaire, but the Study would also consider this information being requested as part of the Consent Form or a separate Contact Details Update Form.
- Fields that must be included are: Title; First Name; Last Name; Street Address; Town / Suburb; State; Post Code; and Email address. The following statement should be included regarding email address:

  'Extra Contact Details: it would be very helpful and reduce study costs if the 45 and Up Study could contact you in future by email. If you are happy for the Study to do this, please write your email address here'
- Fields that may also be included, space allowing, are: Home Phone Number; Work Phone Number; and Mobile Phone Number.
- Sub-Studies that involve web-based contact with participants may have the option of providing participants with a link to the online contact details update form on the 45 and Up Study website.

8. Required question for sub-study questionnaires

- Sub-Studies including a self-report questionnaire are required to include all three of the following questions, in the specified format:

REQUIRED QUESTION 1:

Has a doctor EVER told you that you have:
(If YES, please cross the box and give your age when the condition was first found)

	Yes	Age when condition was first found
skin cancer (not melanoma)	☐	☐☐age
melanoma	☐	☐☐age
breast cancer	☐	☐☐age
prostate cancer (men only)	☐	☐☐age
other cancer	☐	☐☐age
type of cancer (please describe)		
hear t disease	☐	☐☐age
type of heart disease (please describe)		
high blood pressure	☐	☐☐age
stroke	☐	☐☐age
diabetes	☐	☐☐age
blood clot (thrombosis)	☐	☐☐age
enlarged prostate (men only)	☐	☐☐age
asthma	☐	☐☐age
hay fever	☐	☐☐age
depression	☐	☐☐age
anxiety	☐	☐☐age
Parkinson's disease	☐	☐☐age
none of these	☐	

REQUIRED QUESTION 2:

In the last month have you been treated for:
(If YES, please cross the box and give your age when the treatment started)

	Yes	Age started treatment
cancer	☐	☐☐age
heart attack or angina	☐	☐☐age
other heart disease	☐	☐☐age
high blood pressure	☐	☐☐age
high blood cholesterol	☐	☐☐age
blood clotting problems	☐	☐☐age
asthma	☐	☐☐age
osteoarthritis	☐	☐☐age
thyroid problems	☐	☐☐age
osteoporosis or low bone density	☐	☐☐age
depression	☐	☐☐age
anxiety	☐	☐☐age
none of these	☐	

REQUIRED QUESTION 3:

Are you NOW suffering from any other important illness?

☐Yes ▼ ☐No

Please describe this illness and its treatment

- The justification for the inclusion of this question, if required for ethics submissions or any other purpose, is that it allows the 45 and Up Study to track participant health events over time.