

Guidelines for authors regarding technical review of 45 and Up Study papers

1. The purpose of technical review is to ensure that technical aspects of the submitted work as they relate to the 45 and Up Study are accurate and consistent. In particular this relates to the description of the 45 and Up Study, the Study variables, the Study stakeholders, and the scope of the reported analysis (relative to the approved project). It is not peer-review or statistical review.
2. Technical review is a requirement for all papers reporting analyses of 45 and Up Study data including abstracts for conference presentations and reports. Investigators will acknowledge this requirement when signing their agreement with the 45 and Up Study to receive or be given access to Study data.
3. Investigators will initiate technical review by submitting to the 45 and Up Study coordinating centre <mailto:45andUp.research@saxinstitute.org.au> the **final draft** of the paper/abstract/report in the format ready for submission and the associated 45 and Up Study project number. Earlier drafts will not be accepted.
4. For reports that **do not use** Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data, the 45 and Up Study coordinating centre will endeavour to ensure researchers receive a report from technical review by not later than the tenth working day after submission. Conference abstracts are usually reviewed much faster than this (2-5 working days). Reports that describe analyses using MBS or PBS data need to be reviewed by both the 45 and Up Study coordinating centre and the Department of Human Services (formerly Medicare Australia). Papers will be submitted to the DHS by the 45 and Up Study coordinating centre on behalf of the researchers. The DHS committee meets approximately every two weeks (outside of Christmas and January) and the turnaround time by DHS has usually been three to four weeks but this is not under 45 and Up Study coordinating centre control.
5. Technical review does not include issues covered by scientific peer review. Technical reviewers may, however, occasionally offer suggestions on science or English expression or usage. Authors are not obliged to accept them. However if a technical reviewer identifies a scientific issue that, if not dealt with, might mislead other researchers regarding the 45 and Up Study data, the reviewer may require that a change is made.
6. The technical review process will include an assessment of whether or not the paper is within the scope of the project to which the applicants have linked it. This assessment will be made by comparing the results mentioned in the Abstract with the objectives of the project as described in the application. Lack of a clear relationship between the two will be taken as evidence that the paper is out of scope and may be grounds to not approve the paper and to request that the authors make a new project application or project amendment.
7. If issues are identified at technical review that require significant changes to the items covered by technical review (e.g. scope of reported analysis, Study variables etc.) then the paper may be required to be submitted for further technical review.
8. Table 1 below outlines some requirements authors are expected to adhere to for the technical review and authors should check this list before submitting a paper for review.

Table 1: Sax Institute’s technical requirements for papers reporting results of analyses of 45 and Up Study data

Subject	Technical Requirements for Papers and Reports	Technical Requirements for Abstracts
Mention of the 45 and Up Study	The phrase “The Sax Institute’s 45 and Up Study” and “Australia” must be included in the text (i.e. not just in a footnote) of the paper, usually the Methods, to identify the source of the data.	The phrase “45 and Up Study” must be included in the text (i.e. not just in a footnote) of the abstract, usually the Methods, to identify the source of the data.
Description of the 45 and Up Study population and methods	<p>The 45 and Up Study methods must be accurately described. Researchers using the study should have read the paper that reports the methods in detail and this paper should be cited - <i>45 and Up Study Collaborators. Cohort profile: The 45 and Up Study. International Journal of Epidemiology 2008; 37: 941 – 947.</i></p> <p>An example of a description of the study follows:</p> <p>“The Sax Institute’s 45 and Up Study is based in the population of the state of New South Wales (NSW), Australia. Prospective participants were randomly sampled from the Department of Human Services (formerly Medicare Australia) enrolment database, which provides near complete coverage of the population. People 80+ years of age and residents of rural and remote areas were oversampled. A total of 267,153 participants joined the Study by completing a baseline questionnaire (between Jan 2006 and December 2009) and giving signed consent for follow-up and linkage of their information to routine health databases. About 18% of those invited participated and participants included about 11% of the NSW population aged 45 years and over.”</p> <p>Note that the complete sample size is subject to revision from time to time and will depend on the version of the data researchers received at the time of provisioning.</p>	The number of 45 and Up study participants and the number of time points must be included in the abstract.

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Description of 45 and Up Study participants included in the analysis	Where the analysis is based on a sub-set of participants, the sub-set must be precisely defined by the period of recruitment, if based on a less than complete data release, and in terms of the variables and their values used in selecting it from the whole sample. The sample size actually used for the analysis should be stated.	The number of 45 and Up study participants and the number of time points must be included in the abstract.
Description of the 45 and Up Study variables**	All 45 and Up Study data items used in the analysis must be correctly described. In general, names used for data items should be those in the latest 45 and Up Study Data Book - https://www.saxinstitute.org.au/our-work/45-up-study/data-book/ . For items of particular importance in the analysis, the questions used to elicit the information and their response categories or scale should be described exactly as they appear in the questionnaires - https://www.saxinstitute.org.au/our-work/45-up-study/questionnaires/ . Where a variable used is a derivative of one or more Study data items, the derivation should be fully described or a reference given to where a full description can be found.	All 45 and Up Study data items, when included in the abstract, must be correctly described.
Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data	<p>Linkage of the 45 and Up cohort data to the MBS and PBS data is done by the Sax Institute using a unique identifier that was provided to the Department of Human Services (DHS).</p> <p>Where the analysis includes the use of MBS and PBS data, the Department of Human Services (DHS) must be acknowledged for supply of the data.</p> <p>Users of MBS and PBS data should ensure they are familiar with how these data are collected and the limitations of the data before planning their analyses. More information on the MBS and PBS data are available on the websites: http://www.mbsonline.gov.au/ and http://www.pbs.gov.au/pbs/home.</p>	Where the analysis includes the use of MBS and PBS data, the Department of Human Services (DHS) must be acknowledged for supply of the data.

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Linked data - CHeReL	Users obtaining linked data through CHeReL should refer to the CHeReL website to familiarise themselves with the data linkage process and the data collections used, see: http://www.cherel.org.au/ . Basic details of this process and the data collections should be included in the paper with a reference to the CHeReL site.	When data are linked through CHeReL the datasets used and CHeReL must be mentioned in the abstract.
Description of ethical approval**	<p>Mention must be made of the ethical approvals for the 45 and Up Study as a whole and for the specific analysis, linkage study or sub-study that gave rise to the paper. Thus at least two ethics committees will usually be mentioned. The conduct of the 45 and Up Study was approved by the University of New South Wales Human Research Ethics Committee (HREC). The specific project usually requires the approval of the researchers' home institution and if there is linkage through the CHeReL, the NSW Population and Health Services Research Ethics Committee (PHSREC).</p> <p>Note also the importance of mentioning participant consent as shown in the model <i>Description of the 45 and Up Study population and methods</i> above.</p>	It is acceptable to not mention the ethical approvals for the 45 and Up Study in the abstract however it needs to be mentioned in the conference presentation.

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<p>Statements about representativeness and generalisability of the results of analyses of 45 and Up Study data</p>	<p>Nothing should be said without careful qualification that suggests the prevalence of characteristics or incidence of events in 45 and Up Study participants are representative of corresponding statistics in the NSW or Australian populations of the same age range. The participation rate of ~18% means that great care should be taken if generalising these statistics to the general population.</p> <p>The same level of qualification, however, is not necessary if generalising the parameters of an association between two 45 and Up Study variables or between one 45 and Up Study variable and a data item from a linked data set. The case for a higher level of generalisability of these parameters is made in the following paper based on 45 and Up Study data and could be cited when justifying such a generalisation: Mealing NM, Banks E, Jorm LR, Steel DG, Clements MS, Rogers KD. Investigation of relative risk estimates from studies of the same population with contrasting response rates and designs. BMC Med Res Methodol. 2010;10:26.</p>	<p>Nothing should be said without careful qualification that suggests the prevalence of characteristics or incidence of events in 45 and Up Study participants are representative of corresponding statistics in the NSW or Australian populations of the same age range. The participation rate of ~18% means that great care should be taken if generalising these statistics to the general population.</p> <p>The same level of qualification, however, is not necessary if generalising the parameters of an association between two 45 and Up Study variables or between one 45 and Up Study variable and a data item from a linked data set. The case for a higher level of generalisability of these parameters is made in the following paper based on 45 and Up Study data and could be cited when justifying such a generalisation: Mealing NM, Banks E, Jorm LR, Steel DG, Clements MS, Rogers KD. Investigation of relative risk estimates from studies of the same population with contrasting response rates and designs. BMC Med Res Methodol. 2010;10:26.</p>

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Presentation of results	<p>Results should be presented in ways that strictly limit the risk that a participant or a small community of participants can be identified and some information specific to them disclosed to or inferred by a reader.</p> <p><i>Protecting individual participants</i></p> <ul style="list-style-type: none"> • Individual “cases” must not be described. • Simple statistical descriptions (e.g. percentages or means) must be based on groups of at least five participants. • It must not be possible to read or estimate individual subject’s values from graphical presentations of data. <p><i>Protecting communities</i></p> <ul style="list-style-type: none"> • Small (<1,000 population) or sensitive (Indigenous) communities should not be identified, either directly or indirectly. • Statistics relating to individual small or sensitive communities should not be presented unless they are one of at least five such communities being described. 	<p>Results should be presented in ways that strictly limit the risk that a participant or a small community of participants can be identified and some information specific to them disclosed to or inferred by a reader.</p> <p><i>Protecting individual participants</i></p> <ul style="list-style-type: none"> • Individual “cases” must not be described. • Simple statistical descriptions (e.g. percentages or means) must be based on groups of at least five participants. • It must not be possible to read or estimate individual subject’s values from graphical presentations of data. <p><i>Protecting communities</i></p> <ul style="list-style-type: none"> • Small (<1,000 population) or sensitive (Indigenous) communities should not be identified, either directly or indirectly. • Statistics relating to individual small or sensitive communities should not be presented unless they are one of at least five such communities being described.
45 and Up Study acknowledgements	<p>Conditions of agreements with the 45 and Up Study’s funding partners require appropriate acknowledgement of these partners on all publicly accessible outputs. Since partners may vary over time, the up-to-date text should be obtained from - https://www.saxinstitute.org.au/our-work/45-up-study/for-researchers/. You can access the acknowledgement text under the ‘Steps before publication’ tab.</p>	<p>It is acceptable to not mention the 45 and Up Study’s funding partners in the abstract, however it needs to be mentioned in the conference presentation.</p>