

## THE 45 AND UP STUDY: SUMMARY OF PROTOCOL

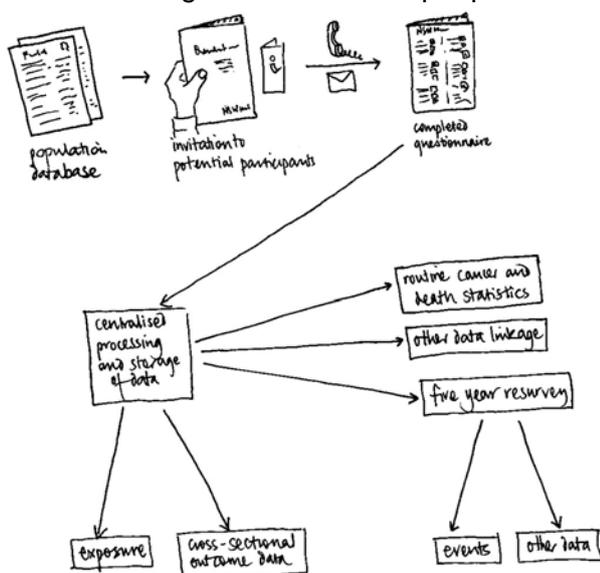
### Background and rationale

Unprecedented changes to the structure of the Australian population are predicted for the near future such that the over 65 age group is likely to increase by around 50% in the next 15-20 years. The rapidity and scale of this population ageing highlights the need for timely and reliable evidence regarding the key factors impacting on the health of older people in Australia. Comprehensive investigation of the determinants of healthy ageing incorporates assessment of disease risk, quality of life and other indices, in relation to a very wide range of possible exposures, including social and psychological factors, with consideration of how these exposures might interact with one another. A large scale cohort study of individuals aged 45 and over will provide information on a wide range of exposures and outcomes of public health importance for the ageing population. At the same time as providing timely and reliable answers to specific research questions, the cohort study will serve as a framework for a range of future research activities and will answer important predictable and unforeseen questions unable to be addressed by other study designs, including the effect of a risk factor on a range of conditions.

### Aims and priority research areas

The aim is to set up a large-scale population-based cohort study of 250,000 individuals aged 45 and over in New South Wales (equal to around 10% of the general population of New South Wales in this age group), to address the following priority research areas and questions and to provide a long term resource for public health research:

1. Examination of the socioeconomic determinants of healthy ageing, including rural/urban inequalities, effect of retirement, social capital and variations in healthy ageing by ethnicity and social class.
2. Investigation of the health effects of obesity, overweight and physical activity, with a particular focus on the risk of cancer, cardiovascular disease, diabetes mellitus and all cause mortality.
3. Investigation of risk factors for and the detection and management of cancer, including investigation of prostate cancer and prostate cancer screening.
4. Investigation of risk factors for and management of cardiovascular disease.
5. Investigation of impact of environmental factors on healthy ageing.
6. Examination of risk factors for mental health problems in later life, including depression, and use of mental health services.
7. Investigation of use of health services in relation to ageing, including the determinants of use of residential aged care.
8. Investigation of health in people 80 and over (the "old old").



### Methods

The project will take the form of a prospective study of at least 250,000 men and women from the New South Wales general population, followed for at least 10 years after recruitment.

**Recruitment:** A broadly random sample of the New South Wales general population aged 45 and over will be asked to join the study by returning a self-administered questionnaire and providing written consent for follow-up. There will be oversampling of those aged 80 and over and of rural residents.

**Follow-up:** Participants will be followed for incident cancer diagnoses and cause-specific mortality through the New South Wales cancer

registry, the National Cancer Statistics Clearing House and the National Death Index. Opportunities for other types of data linkage, such as linkage with New South Wales hospitalisation

data, emergency department data, and the Pharmaceutical and Medical Benefits Schemes, will be explored and used where practicable. Participants will be sent a follow-up questionnaire approximately every five years after recruitment to ascertain incident self-reported morbidity and current health status, to update exposure data and to gather new exposure data. Participants' reports of incident morbidity will be validated and additional evidence of disease will be sought to allow classification of disease status according to standard criteria.

**Analysis, numbers of events and power:**

Following initial analyses of cross-sectional data, the main means of investigating relationships between exposure and outcome will be through a series of case-control studies nested within the cohort. For conditions yielding at least 3,500 incident cases or deaths (e.g. diabetes mellitus, myocardial infarction, stroke, colorectal cancer, prostate cancer, breast cancer, hip fracture, dementia) the study will be able to detect a minimum relative risk of 1.3 for exposures affecting 10-90% of controls and 1.4 for exposures affecting 5-95% of controls, with 95% power and 1% significance. With the same power, significance and ratio of cases to controls, for outcomes with 1,000 or more events (e.g. ischaemic heart and cerebrovascular disease deaths and incident Parkinson's disease, non-Hodgkin's lymphoma, lung cancer) the study should be able to detect minimum relative risks of 1.4-1.5 for exposures affecting 20-80% of the population and 1.6 for exposures affecting 10-90% of the population.

**Table: Estimated numbers of events among a cohort of 250,000 people in New South Wales, aged 45-79**

Condition	total number of new cases expected at follow up after:	
	5 years	10 years
Colorectal cancer	2350	5500
Prostate cancer	2350	5600
Breast cancer	1900	3900
Melanoma (skin)	1300	2850
Non-Hodgkin's lymphoma	550	1350
Diabetes mellitus	3100	5850
Myocardial infarction	2750	6400
Stroke	2350	6050
Hip fracture	1400	4000
Total deaths	6150	16500

**Confidentiality**

All data will be handled in strict accordance with the relevant privacy legislation and used for health research only. All identifying details will be stored separately from the other data recorded for each participant and linkage of participant identifying information with their other study data will take place only when strictly necessary. Guidelines for such linkage will be drawn up by the Steering Committee prior to commencement of the study. Data released for analyses will not contain identifying information and no publication from the study will identify individuals taking part. Participation in the study will be purely voluntary.

**Use of the study by the research community**

The study is designed as a collaborative research resource which is available for use by the wider research community. Researchers will contribute to the design, development and conduct of the study through a dedicated research network. Researchers will apply to use data from the study, via a pre-defined and rigorous process of peer review and will also be in a position to set up specific "sub-studies" within the framework of the cohort. By making data available to the scientific community, the project will serve as a means to develop national expertise and infrastructure in large scale health research. It will provide a focus and resource for high quality research over the coming decades.

**Expected outcomes and contribution to knowledge**

The 45 and Up Study represents a substantial, broad and accessible investment in public health research. By addressing issues which are relevant to the Australian context and utilising unique aspects of the Australian setting, including unique opportunities for data linkage, the 45 and Up Study is expected to produce findings of national and international importance.