

The ACT Asbestos Health Study: Protocols

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For ACT Health

The ACT Asbestos Health Study

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1. Synopsis

The ACT Asbestos Health Study will investigate the potential health effects of living in a house with loose-fill asbestos insulation in the Australian Capital Territory (ACT), referred to throughout as affected residential premises (ARPs). The study will provide information on mesothelioma in the ACT, domestic exposure to asbestos and health concerns of current and recent residents of ARPs, and estimates of the risk of cancers associated with living in an ARP. There are four components to the study:

1. A descriptive analysis of mesothelioma cases diagnosed in the ACT since 1982.
2. Focus group discussions to determine the health-related and social concerns of current and recent residents of ARPs.
3. Cross sectional survey to assess health-related concerns and determine likely levels of exposure to asbestos insulation in current and recent residents of ARPs.
4. Data linkage study to estimate the relative rates of mesothelioma and other cancers in current and former residents of ARPs.

2. Abbreviations, acronyms and terminology

ACT—Australian Capital Territory

ANU—The Australian National University

ARPs—Affected residential premises

NCEPH—National Centre for Epidemiology and Population Health

NSW—New South Wales

Throughout the protocol, where ‘residents of ARP’ are referred to, this implies both current and recent residents who were registered with the ACT Asbestos Response Taskforce at 28 October 2014 when the ACT Government announced the buyback scheme for ARPs. Where residents who lived in ARP prior to this time are included in the study they are referred to as ‘past residents’.

3. Introduction

Asbestos is a naturally occurring silicate mineral that occurs in a variety of fibrous forms. The fibres have heat-resistant properties and have been used commercially in cements, insulation, and other building materials. Inhalation of asbestos fibres can cause fibrosis (asbestosis), lung cancer and mesothelioma. The main forms of asbestos include chrysotile, actinolite, amosite and crocidolite, which vary in their propensity to cause disease in humans.

The association between exposure to asbestos and the health outcomes of pleural and peritoneal mesotheliomas and lung cancers is well understood for people exposed in an occupational setting. [1] However, the health impact of exposure to asbestos in domestic settings is less clear. [2] Asbestos-based insulation has been recognized as a potential health concern, but there is very little scientific data to examine potential health risks. [3] Non-occupational exposure has been suggested to explain up to 20% of mesotheliomas in developed countries. Australian researchers have raised concerns that it may be important to consider exposure to asbestos in the domestic setting as a cause of mesothelioma. [4] Exposure to asbestos in the domestic setting is likely to occur mainly through renovation work. [4, 5]

Loose-fill asbestos insulation in the ACT

The ARPs were insulated by a contractor that is commonly known as ‘Mr Fluffy’. The contractor used loose-fill amosite (and sometimes crocidolite or blue) asbestos in a ground raw form in homes in the ACT and the southern region of NSW and operated in the ACT between the late 1960’s and 1979. Between 1988 and 1993, approximately 65,000 houses in the ACT were visually checked for the presence of loose-fill asbestos insulation. Approximately, 1,100 houses using loose-fill asbestos insulation were remediated by removing insulation through an extensive program. Recently, there have been enhanced concerns after asbestos fibre counts were identified in remediated houses. Additionally, there have been recent reports in the media of mesothelioma in previous residents of ARPs and in an electrician who worked on the ARPs, although exposure histories have not been verified.

In June 2014, the ACT government established The Asbestos Response Taskforce (<http://www.act.gov.au/asbestos-response-taskforce>) to respond to impacts of loose-fill asbestos insulation on residents and the ACT community. The Taskforce reports directly to the Chief Minister of the ACT and represents a single point of contact for ACT residents concerned about loose-fill asbestos insulation. The Taskforce has a mechanism for recording the contact details of current and former residents of affected houses as well as members of the wider community such as tradespeople who are concerned about their exposure to asbestos in affected houses.

Rationale for examining the health effects of living in ARPs

In response to community concern about health risks, ACT Health considered the potential physical and psychological health and related social effects of living in these houses, along with the risk of developing mesothelioma. The ACT situation is unique in that raw amosite asbestos was used as an insulating material and despite remediation it was still able to be found in the household environment many years later. ACT Health requested that the ANU develop a staged multi-component research approach over a two year period. The research was to address several

key questions about the distribution of mesothelioma in the ACT, the health concerns of residents of an ARP, likely levels of exposure of residents to asbestos insulation, and the risk of developing mesothelioma in recent and former residents of an ARP. ACT Health contracted ANU to conduct the ACT Asbestos Health Study, which will provide an independent assessment of health risks from living in an ARP in the ACT.

4. Component 1: Descriptive Study of Mesothelioma in the Australian Capital Territory (ACT)

4.1. Objectives

The objective of this study is to describe the rates and distribution of mesothelioma in the ACT from 1982 to 2014 and compare mesothelioma rates in the ACT to those for the rest of Australia (excluding WA).

4.2. Hypotheses

The specific hypotheses under study are that:

1. Mesothelioma rates in the ACT are higher in men than women.
2. Mesothelioma rates in the ACT have increased over time.
3. Mesothelioma rates in the ACT do not differ from those reported for the rest of Australia (excluding WA).^{ab}

4.3. Study design

This is a descriptive study of the distribution of mesothelioma in the ACT from 1982 to 2014. The number of cases and rates will be reported in relation to age, sex, area-level socio-economic status (SES) and year. Mesothelioma rates will be compared to those for the rest of Australia (excluding WA). WA is excluded from the comparison given rates in WA are substantially higher than elsewhere in Australia due to the large number of cases associated with asbestos mining at Wittenoom. We will also report the number of people diagnosed with mesothelioma who were residents of an ARP at the time of diagnosis.

4.4. Study population

The study population is ACT residents. The study will include all cases of mesothelioma reported to the ACT Cancer Registry between 1982 and 2014.

The Registry maintains a record of all cases of malignant cancer diagnosed in ACT residents. Registry data date back until 1982, however only since 1994 has reporting been mandatory, with all public and private pathology laboratories, hospitals, radiation oncology clinics and nursing

^a WA is to be excluded from the comparison as the rates in WA are much higher than elsewhere due to the large number of cases associated with asbestos mining at Wittenoom.

^b No hypothesis is given in relation to living in an ARP at the time of diagnosis as this does not reflect exposure history, only residence at time of diagnosis.

homes in the ACT required by law to notify the ACT Cancer Registry of cancer in people or human tissues. [6] As the quality of the data is likely to be compromised by incomplete reporting prior to 1994, data will be reported separately for the two periods, i.e. 1982–1993 and 1994–2014.

4.5. Study procedure

Data sources

De-identified ACT Cancer Registry data will be requested through ACT Health. The Registry contains information on sociodemographic characteristics of the patient at the time of diagnosis (including age, sex and postcode), as well as clinical details about the cancer and if a person has died, date of death (see table in Appendix 1). Cancer type is coded according to the International Classifications of Diseases of Oncology, Third edition (ICD-O3), with morphology codes used to extract the mesothelioma cases for this study. Details of the variables requested are in the attached Data Request (Appendix 2).

In addition, addresses of the cases in the ACT Cancer Registry will be linked to the ACT Asbestos Response Taskforce register of ARPs to determine whether or not patients were residents of an ARP at the time of cancer diagnosis (yes, no). This linkage will be performed by ACT Health and only de-identified data will be supplied to the researchers analysing the data.

For calculation of rates (i.e. number of cases per 100,000 population), population counts will be obtained from ABS published estimates. [7] To compare mesothelioma rates with those for the rest of Australia, we will use publicly available cancer data (mesothelioma cases reported by age, sex and year), from the Australian Institute of Health and Welfare (AIHW) [8] and from the NSW Cancer Registry. [9] We will obtain the WA mesothelioma data by making a standard data request to the WA Cancer Registry (<http://www.health.wa.gov.au/wacr/home>).

Cases

The study will include all cases of mesothelioma diagnosed by 31 December 2014 that were recorded in the ACT Cancer Registry as of time of receiving the data.

Variables

Variables to be included in the analyses are: *sex* (male, female); *age group*, based on age at diagnosis (categorised into age groups, depending on the number of cases); and *period*, based on year of diagnosis (aggregated, depending on the number of cases per year). We will also examine the distribution of cases by *area-level SES*, based on the Socio-Economic Indexes for Areas (SEIFA) Index of Relative Socioeconomic Disadvantage (IRSD); [10] the score will be derived from postcode of residence, and categorised into ACT-population-based tertiles, using the most recent version of the SEIFA (2011). *Survival time* will be calculated as the number of days between date of diagnosis and date of death (categorised as <1 year, 1–<2 years, 2–<5 years, and ≥5 years).

4.6. Data analysis

Raw data

For the ACT, we will report the crude number of cases by age, sex, area-SES and year, as well as the total number of cases where mesothelioma was diagnosed in a person resident at an ARP at the time of diagnosis.^c

Crude incidence rates and cumulative mortality rate

For a given year (i.e. across all age groups combined), we will calculate the crude mesothelioma incidence rates for the ACT (using ABS population data [7] for denominators) for the total population, and separately in males and females; depending on sample size, we will also calculate rates by area-SES. In addition, using the date of death field in the Registry to identify mesothelioma deaths, we will calculate median survival time (and interquartile range) and the proportion dying within 1, 2 and 5 years of diagnosis, amongst eligible cases (i.e. for people diagnosed before 2014, 2012 and 2010, respectively).

Modelled trends

To investigate trends over time, we will perform regression analysis. Prior to the modelling procedure, we will use indirect standardisation to calculate the expected cases for each year, using the age- and sex-specific rates for Australia (excluding WA) in 2001 (or 2000–2002) as the standard. The observed and expected cases for each year will then be used in the regression analysis. Assuming cases are Poisson distributed within each year, we will regress observed cases on year using a log link, with the log of expected cases as an offset. Similarly, we will use Poisson regression to compare trends in ACT rates to those for the rest of Australia (excluding WA). For these models we will use the age- and sex-specific rates for Australia in a given year as the standard.

All analyses will be performed using Stata version 13 (StataCorp).

Power calculations

Power calculations for comparison of ACT and Australian incidence rates. Based on the fact there were 22 incident cases of mesothelioma in the ACT for the period 2002–2006, [11] and assuming that the Poisson counts in the ACT are reasonably stable, with 5% significance and 80% power, then the one-sided detectable rate ratios would be 0.64 for lower rates and 1.4 for higher rates in ACT compared with the expected counts from Australian rates. These would be moderately strong changes to observe.

Power calculations for temporal trends in the ACT compared with 2001 age-specific rates. Comparing rates across five-year periods, and assuming no changes in the age structures, with

^c Subject to approval from Dr Paul Kelly, CHO to report small cell sizes.

5% significance and 80% power we could observe a rate ratio of less than 0.3 or greater than 2.1 for another five-year calendar period.^d There will be less power to assess whether there has been a change in trend in the ACT compared with the national trends.

4.7. Ethical issues

This project has been approved by the ACT Health Human Research Ethics Committee (ETH.11.14.330, approved 12/12/2014) and the ANU Human Research Ethics Committee (Protocol no. 2014/808, approved 25/03/2015).

Ethical issues around confidentiality, privacy, security and consent have been detailed in the both Ethics Committee applications (see Appendix 3 for copy of ANU Ethics Submission) and in the ACT Health 'Waiver of Consent' request (Appendix 4).

^d The national rates for mesothelioma have been comparatively stable for the period 2000–2010, being approximately double the rates observed in the 1980s. A similar pattern could be observed in the ACT, suggesting that we could detect a change from the 1980s to today, but that we may be unlikely to detect a sufficient change in recent years.

5. Component 2: Focus Group Discussions with residents of affected residential premises

5.1. Objectives

The primary objective of the study is to determine the health-related and social concerns of residents of ARPs.

The related aims of the focus group discussions are to:

1. examine the range of experiences and opinions of people living in, or owning, an ARP;
2. understand residents' perceptions of risk from exposure to asbestos in order to inform ways to assist affected residents (e.g. provide further information or mental, social or health services or other support);
3. inform policy responses regarding risk communication relating to environmental threats, to reduce anxiety where possible; and
4. inform the development of a questionnaire for a future survey of residents.

This study is predicated on the understanding that health-related concerns are also social in nature. The difficulties and concerns that residents may experience are likely to be due in large part to the social context in which they will have to manage their situation. For example, moving houses, relocating children, talking with neighbours and being made aware of media-related information are all socially mediated interactions that may provoke feelings of stress, anxiety, or relief with potential health risks or benefits. The notion that residents have health-related concerns that are separate from their social world is unlikely to reflect their experiences or concerns.

5.2. Study design

A selection of people from the ACT Asbestos Response Taskforce register of people owning or living in an ARP will be invited to participate in a group discussion. Because the topic is quite specific (i.e. living in an ARP) and has already been widely discussed in the media, we anticipate that two groups will contain enough knowledgeable and interested people to obtain a range of views. Focus group discussions are not expected to be representative. Ideally a focus group consists of about 6–12 people but can be larger. To obtain this number we will invite 80 people to participate, expecting that less than half will attend. We expect that the groups will consist of a mix of men and women (including some with children), and home owners and renters, to cover the mix of views. The invitation letters (Appendix 5) will ask residents to email or phone researchers to register their interest in participating in a group, allowing researchers to monitor

and adjust the composition of the groups as they go along. If groups are unbalanced (for example no renters) invitations can continue to be sent out until the shortage is rectified.

Both discussions will be held in a club venue (to be confirmed); one discussion will be held in North Canberra and the other in South Canberra, to ensure that they are easily accessible to those living all over Canberra. Focus groups work best when there are two people running the group; one to moderate and the other to observe, note and assist. Therefore a senior experienced researcher from the ACT Asbestos Health Study team will moderate the groups with the assistance of another experienced researcher to observe and note.

5.3. Study population

The focus group participants will be recruited through their registration on the ACT Government's Asbestos Response Taskforce list. The ACT Asbestos Response Taskforce has confirmed that it will coordinate access to the contact details for all registered residents of ARPs. Residents will be randomly selected from this list and asked to participate in the focus groups via a letter sent to their current address. Participation is entirely voluntary and participants are free to withdraw without consequence at any time.

5.4. Study procedure

The focus group study will be conducted to minimise breaches in privacy and confidentiality. Focus groups will require participant consent (Appendix 6) and the manner in which they are conducted will be clearly explained to participants. The discussions will be audio-recorded. Participants will be asked to use a pseudonym and any identifying information about participants will be deleted before sending recordings to transcribers.

The key outcome of the focus group study would be an understanding of the health and social concerns of residents and their perceptions of the risks of asbestos contamination. Findings from the focus group discussions will be used to develop questions for the cross-sectional survey (Component 3 of the study) and will be combined with results from other components of the study to inform policy responses.

In addition to the focus group discussions, a brief one page questionnaire (Appendix 7) will be distributed to collect basic socio-demographic data, such as age, gender, marital status, employment and number of children. These data will allow us to describe the composition of the groups, although we do not expect the group participants to be representative of all residents.

All research staff and staff from the transcribing service will sign a Confidentiality Deed supplied by the Territory. Data will be stored on secure servers at the Australian National University for five years.

It is expected that the focus group discussions will be held in July 2015, and each will be no longer than 2 hours in length.

5.5. Data analysis

Analysis of the focus group data will be thematic and will not identify individuals. The discussions will be audio-recorded and professionally transcribed by a transcribing service. Once transcriptions are available, experienced qualitative researchers will identify codes (using ATLAS.ti) to assist in the management of data. A code list will be developed based on an initial reading of the transcripts and once the team have discussed and agreed on them, the list of codes will be used to analyse the transcripts. The codes and resultant themes will reflect both the interview topics and emergent ideas. This approach is based on a modification of Strauss and Corbin's grounded theory methodology. [12]

5.6. Ethical issues

Ethical issues specifically relate to the risks and benefits of participating in a focus group. These usually include concerns about anonymity and protection of privacy and the potential harms associated with participation. The study will have ethics approval and oversight from the Human Research Ethics Committees of both ACT Health and the ANU and any other interstate committees as required.

Potential participants will be randomly selected from the list of residents of ARPs to receive an invitation to attend one of two focus group discussions. The invitation will be posted to their current address and participants will be informed that they are under no obligation to attend the meeting. They will also be informed that they can withdraw from the discussion at any time or choose not to answer any question that they perceive to be sensitive.

Study investigators conducting the group discussions are trained and sensitive to potential issues. They will manage the group to avoid one person dominating the discussion and provide space for less forthright members to voice their opinions if they wish. If study participants become upset discussing the impact of living in an ARP on their lives more broadly, they will be referred to mental health support services recommended by the ACT Asbestos Response Taskforce, including the NewAccess and HealthinMind programs.

6. Component 3: The ACT Asbestos Health Survey—A cross-sectional survey

6.1. Introduction to the survey

In this cross-sectional study, we will survey people who have lived at ARPs to ascertain health-related concerns and likely levels of exposure to asbestos insulation.

6.2. Objectives

The primary aims of the ACT Asbestos Health Survey are to:

1. assess the health concerns of residents of ARPs, and
2. measure levels of psychological distress in residents and compare these to the general ACT population.

The secondary aims of the study are to:

3. identify the likely exposure levels to asbestos of residents in terms of years lived at an ARP, and
4. assess the prevalence of high risk activities for exposure to asbestos insulation among residents, such as renovation.

6.3. Research questions

The specific research questions that the ACT Asbestos Health Survey aims to answer are, among residents of ARPs:

1. What are the concerns regarding possible health problems associated with living in a Mr Fluffy house?
2. What are the current levels of psychological health distress and how do these compare to the general ACT population?
3. What is the average amount of time spent living at an affected residence?
4. What is the prevalence, nature and scale of high-risk asbestos-related activities, such as renovation and entry into the roof space and/or sub-floor areas that residents have undertaken?

6.4. Study design

The ACT Asbestos Health Survey is a cross-sectional survey that will provide a snapshot of the health experience and potential exposure of residents of ARPs in the ACT. The study's source population is all 1,022 known affected households, which includes all household members aged 18 years and over.

Residents are defined as:

- ‘Current and recent residents’—those who have recently lived in an ARP and were registered with the ACT Asbestos Response Taskforce at 28 October 2014 when the Buyback Scheme was announced by the ACT Government. This includes people who were tenants of an ARP at this time.
- ‘Past residents’—other residents who lived in an ARP at some time in the past and provided contact information to the ACT Asbestos Response Taskforce.

Non-response is a significant problem for cross sectional surveys, as the characteristics of people who respond are usually different than those who do not. [13] This potentially introduces bias to study findings, necessitating strategies to improve response rates and account for non-response in analysis. [14] It is difficult to know what proportion of people approached to participate in the ACT Asbestos Health Survey will contribute information. Where possible, results of the study will be weighted to the known postcode distribution of ARPs in the ACT, to account for potential non-participation among residents. Ideally, study data would be weighted based on the known characteristics of the population, i.e. all residents of ARPs. However, this is unknown and post-sample weighting to postcode will allow a reasonable extrapolation of findings to all residents of ARPs.

6.5. Study population

The study population is all current and recent residents of households registered with the ACT Asbestos Response Taskforce as at 28 October 2014—the date when the buy-back of ARPs was announced by the ACT Government. The primary unit of data collection is persons in the household—defined as ‘one or more persons, at least one of whom is at least 15 years of age, usually resident in the same private dwelling’ (<http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/1286.0~2014~Main%20Features~Underlying%20Concepts~11> accessed 10 May 2015). There are 1,022 known ARPs in the ACT, around 120 of which were tenanted rather than owner-occupied on 28 October 2014. The total number of residents in ARPs is unknown, but the average number of persons per ACT dwelling is 2.8 adults with 0.5 children per household (www.censusdata.abs.gov.au accessed 10 May 2015). The study population includes both owner-occupied and tenanted households. All adults (i.e. those over the age of 18 years) will be eligible to provide information as part of the survey. Where there are children living in the house, an adult identifying as the main carer will be asked to provide information on these children.

In addition, we will invite past residents who have recorded their contact details with the ACT Asbestos Response Taskforce to complete a similar survey that explores health concerns and period of exposure at an ARP. As these respondents will have lived at ARPs for varying lengths of

time and over different time periods, it will not be possible to identify a denominator population for this group.

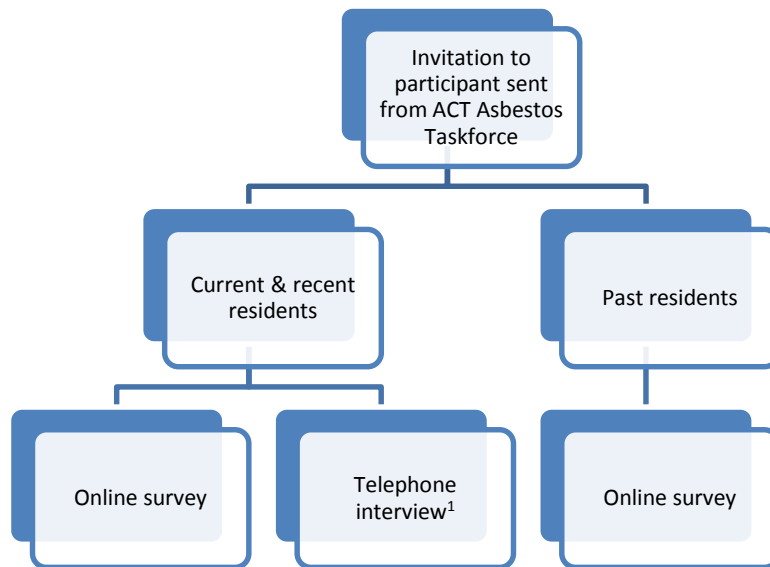
6.6. Reference population

The reference population for the ACT Asbestos Health Survey is the ACT population living in private residences. It may be possible to compare results from the survey for specific health outcomes (e.g. self-assessed overall health, psychological distress) to other studies, such as the PATH project (<http://crahw.anu.edu.au/research/projects/personality-total-health-path-through-life> accessed 10 May 2015). The PATH study is a population-based cohort study in Canberra and Queanbeyan that was sampled from the electoral role in three waves. [15] PATH followed up the wellbeing of approximately 7,500 adults aged between 20–64 years old over a period of 20 years. A potential limitation with comparing the ACT Asbestos Health Survey results with the PATH study include the restricted age-ranges of PATH and the fact that recruitment occurred >10 years ago. Other potential sources of reference data, which are more recent and representative, are the ABS Australian Health Survey (number of ACT residents = 1,725 in 2011–12) (<http://www.abs.gov.au/australianhealthsurvey>) and the ACT General Health Survey that surveys an average of 1,300 ACT residents annually (<http://www.health.act.gov.au/datapublications/reports/chief-health-officers-report-2014>).

6.7. Study procedure

A schematic overview of the study is shown in Figure 1, which is explained in more detail in the sections below.

Figure 1. Schema showing the conduct of the cross sectional study



¹ This group includes only those registered with the ACT Asbestos Response Taskforce who have indicated a preference to receive information in hard-copy or via telephone.

6.8. Invitation to participate

The study team will send an email invitation/letter to residents to participate in the survey in September 2015. The ACT Asbestos Response Taskforce will send out the email/letter to the named household contact person for each residence on behalf of the study team. An accompanying letter will outline the rationale for the study, the potential risks of participation, details of study investigators, and information about the overarching study. A sample letter of invitation is attached at Appendix 8.

The email invitation will contain a unique household identification number (HIN). The unique HIN will assist with identifying the specific ARP and the household to which respondents belong. The registered household contact will be invited to complete the online survey, which will consist of two parts. The first part will include questions about the household, the second part will include questions about the individual respondent's exposure and well-being (see Appendix 9). The invitation letter will request that the household contact ask other household members over the

age of 18 to also complete the second part of the survey, with the main carer of children asked to complete the second part of the survey for people between the ages of 5–18 years.

The ACT Asbestos Response Taskforce will send a hardcopy letter to households where the primary means of communication is in writing. A hardcopy of the survey form will be sent to people receiving written communication, which will be followed by a telephone interview in the days following receipt of the letter.

At the end of the survey, we will request permission to collect the respondent's full name, address, Medicare number and date of birth to allow matching of survey data to disease outcomes in the future (subject to appropriate ethics approvals)

6.9. Respondent participation

Response rates to surveys have been declining over time throughout the world. In this instance, we expect the response rate to be relatively high due to the relevance of the survey to survey participants. We estimate that the response rate (the proportion of at least one household member responding) will be over 60%.

To maximize participation in the survey, we will:

- Contact each registered resident 4 times^e for those who have not responded to the online survey, or the telephone survey.
- Promote the survey through the ACT Asbestos Response Taskforce newsletter in the months leading up to the survey.
- Prepare media releases indicating that the survey is underway when the emails are sent out.

6.10. Survey conduct

The survey data will be collected by:

1. Computer Assisted Telephone Interview (CATI) for respondents who prefer not to complete the survey online (estimated 10% of study population), or
2. an online form using either Lime Survey or Qualtrics survey tool.

^e We will contact residents twice during the afternoon/early evening, and twice during the weekend to ensure that we make every effort to contact people. The interval between reminding people to respond will be 5 days between contacts.

The survey data collection will be piloted on a small sample of current and former residents to ensure that the process is reliable and valid. A market research company will conduct the CATIs.

6.11. Survey instrument

The survey will collect a range of information, including:

- Demographics (age, sex, Indigenous status, marital status, country of birth, language spoken at home, educational attainment, occupation, number of residents in household)
- Tenure: Rental/Owner status
- Amount of time at address
- Housing unit type: single family/multi family
- Exposure (renovation DIY or NOT DIY)
- Children
- Smoking status
- Self-assessed overall health
- Level of distress Kessler 6 Psychological Distress scale (K-6)/Distress Questionnaire (DQ-5) plus Patient Health Questionnaire (PHQ-2) and Generalised Anxiety Disorder scale (GAD-2)
- Perceived economic impact
- Perception of dissemination of health information by the ACT Government (risk communication)
- Household income
- Whether they are happy to for the study team to access their asbestos testing result for the house
- Whether they are happy to be contacted in the future for further health studies relating to living in an ARP.

The questionnaire will be developed based on findings from Component 2 Focus Groups. The questionnaire will be tested among study team members to ensure that the questionnaire is functional and easily understood. Following this, the survey will be piloted using people not familiar with the study, such as past residents of ARPs, or members of the ACT community. An outline of variables that may be included in the survey questionnaire are detailed in Appendix 9. Where possible, relevant questions will be identical to those used in other surveys of the reference population (i.e. PATH, ABS Australian Health Survey, ACT General Health Survey) to enable comparisons of results.

6.12. Data analysis

In the survey, we aim to collect information about all members of the study population (estimated number 2,867). While some other members of the source population who are not members of the study population (i.e. not current or recent residents of ARPs) may be invited to participate, their survey responses will not be included in primary analyses.

We will compare health related to psychological distress in the sample to population-based normative data. The study team will score K-6 using traditional means [16] present mean scores and proportions of respondents who fall into each category of distress (none, mild-moderate, high). We will also use the DQ-5 to identify the proportion of respondents likely to be meeting criteria for a mental health problem. We will quantify the associations between psychological health outcomes and various characteristics of survey respondents, such as time in the premises, owner versus tenant, whether the respondent has done renovations or accessed the roof space/sub-floor, and where asbestos was detected.

The Personality & Total Health (PATH) Through Life study in the ACT was a large population-based cohort study examining the lifespan course of depression, anxiety, and other factors in ACT and NSW residents aged between 20–64 years old. It may be possible to compare ACT Asbestos Health survey data to PATH study normative data on the mental health and wellbeing of the ACT community. It is unlikely that survey results would be able to be linked to PATH houses to examine changes over time, as only an estimated 5 participants in PATH would have been residents of an ARP at best.

For sample size calculations, assume that we will estimate proportions within the study population. The design effect from post-stratification and clustering by household will be approximately 1.5. If we assume a prevalence of psychological distress of 10% in the general population and a prevalence of 16% in the affected residents, with 5% statistical significance and 80% power and conservative assumption of a sample size of 300^f, we will be able to detect a significant difference. In practice, this shows that a subset of the survey defined by a broad age group and by sex will have reasonable power to detect an odds ratio of 1.7 compared with published estimates.

We will make an informal comparison of the prevalence of home renovation among residents of ARPs to published data for New South Wales residents. [5] Data on home renovations from the ACT Health Asbestos Survey may prove useful for future risk assessments.

^f Sample size = sample size assuming simple random sampling x design effect = 200x1.5

Data on respondents who were ‘past residents’ of ARPs will be described, but will be difficult to compare due to the lack of a denominator.

The data will be analysed using Stata version 13 (StataCorp). We will prepare simple frequencies of descriptive variables that are adjusted post-survey for non-participation. We will post-stratify the survey weights by age and sex to have the same distribution as the Mesh Blocks^g which include the ARPs. We will incorporate the survey weights and household as the primary sampling unit in the statistical analysis using Stata survey commands.

6.13. Ethical issues

Privacy and confidentiality

The first page of the survey will outline the nature of the survey, the risks of participation, the options for non-completion and include a statement of consent for collection of information.

At the end of the survey, the respondent will be asked if they are willing to participate in future research. If they indicate yes, they will be asked to provide their full name, Medicare number, date of birth, and contact details. This will be used in future studies of the association between exposure to asbestos and disease (subject to appropriate approvals). Survey respondents will also be asked if they have any air monitoring data they would be happy to provide a copy of to the study team for future use in risk assessment. The survey will request specific detail about results of air monitoring and dust analysis.

The data will be stored on secure servers at the ANU with access restricted to authorized personnel. All personnel associated with the survey, including market research company staff, will sign a Confidentiality Deed supplied by the Territory.

Ethics

The ACT Asbestos Health Survey will be submitted to the ACT Health Human Ethics Committee and the ANU Human Health Ethics Committee.

^g Mesh Blocks are the smallest geographical area defined by the ABS. The 2011 Australian Statistical Geography Standard (ASGS) contains 347,627 Mesh Blocks covering the whole of Australia without gaps or overlaps

7. Component 4: Data Linkage Study on the risk of mesothelioma and other cancers

7.1. Objectives

The primary objectives of this study are:

1. To estimate the incidence of mesothelioma (absolute rate) in people who have lived in an ARP.^h
2. To estimate the relative rate of mesothelioma in people who have lived at an ARP compared to those who have not lived at an ARP.
3. To estimate the relative rate of mesothelioma in people who have lived at an ARP compared to the rate in the general population.
4. To estimate the projected incidence of mesothelioma in people who have lived at an ARP.

Secondary objectives are:

5. To estimate the absolute and relative mesothelioma death rates in people who have lived at an ARP.
6. To calculate the absolute and relative rates of developing other types of cancers associated with asbestos, including lung, ovarian, laryngeal, pharyngeal, stomach and colorectal cancer [17] in people who have lived at an ARP.

7.2. Hypotheses

The null hypotheses are:

1. Rates of mesothelioma, and mesothelioma mortality rates, in people who have lived at an ARP will be the same as those in ACT residents who have not lived at an ARP (after taking into account age and sexⁱ),
2. Rates of mesothelioma in people who have lived at an ARP will be the same as those in the general population (after taking into account age and sexⁱ).
3. Rates of other types of cancers potentially associated with asbestos—lung, ovarian, laryngeal, pharyngeal, stomach and colorectal cancer—will be the same in those who have lived, and in those have not lived, at an ARP in the ACT (after taking into account age and sexⁱ).

^h Note that while incident rates among the exposed can be estimated and compared with non-exposed individuals, there will be considerable uncertainty around these estimates due to the likely small total number of mesothelioma cases.

ⁱ If possible, we will also make crude adjustments for socioeconomic status and smoking, based on survey-based estimates in the relevant populations.

7.3. Study design

A range of possible study designs have been considered for this data linkage study. Investigation of the feasibility of the different designs continues, and while more than one approach may be adopted, the main study design proposed at this stage is a cohort study, involving linking data from Medicare, the ACT Asbestos Response Taskforce records, and cancer and death registries (see Figure 2). Initial discussions with the Data Linkage Unit and Data Integration Services Centre Unit at the Australian Institute of Health and Welfare (AIHW) indicate that this study is, at least in principle, feasible. The following protocol outlines the methods for this study. In section 7.8, we present an additional study design – a nested case-control study.

7.4. Study population

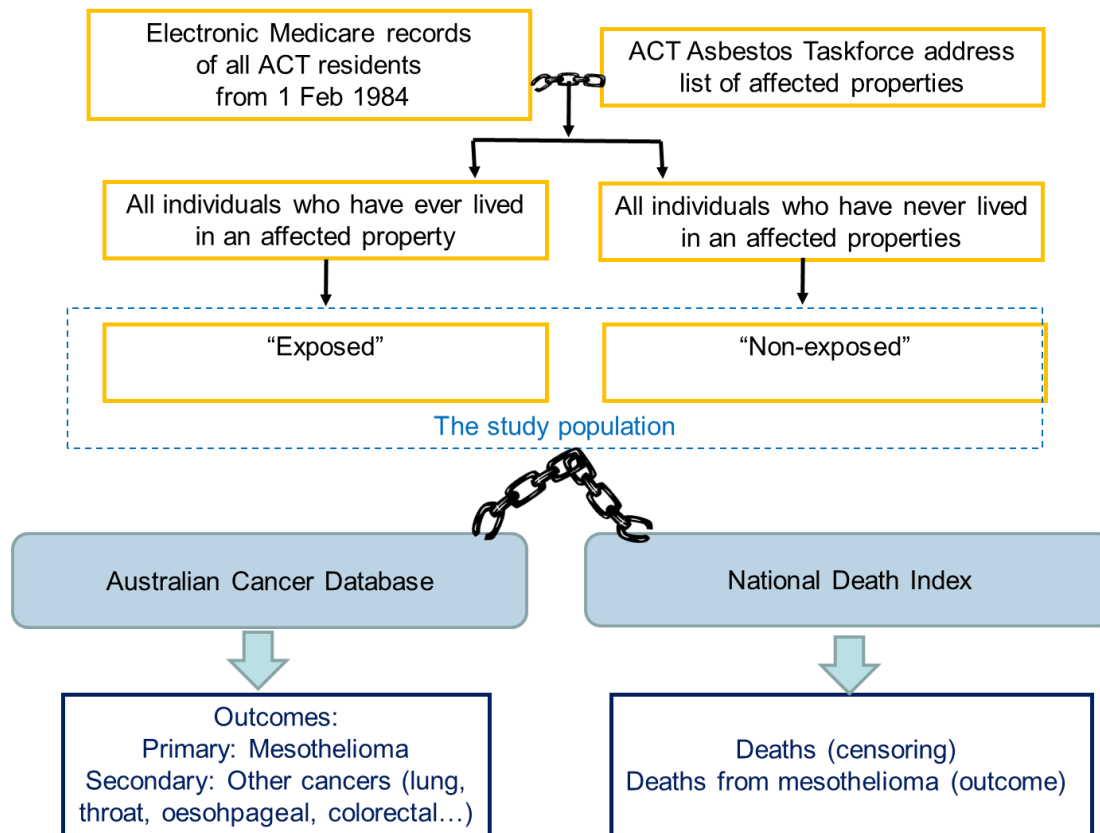
The study population is all people living in the ACT and registered with Medicare between 1984 and 2014.^j

7.5. Study procedure

Individual-level data from the Medicare register will be linked to the ACT Asbestos Response Taskforce register of ARPs, the Australian Cancer Database (ACD) and the National Death Index (NDI) (2012) (see Figure 2).

^j Note that while the population of interest is anyone who has resided in the ACT since loose-fill asbestos was first installed in Canberra homes, i.e. since 1968, there are no databases dating back to 1968 that capture names and addresses of all ACT residents (both adults and children), nor any from which incident mesotheliomas might be identified before 1982 or deaths from mesothelioma easily identified before 1980. See Section 8 (nested case-control study) regarding the possible use of electoral records to identify adults who have ever lived in at an ARP.

Figure 2. Overview of study design



Data sources

ACT Asbestos Response Taskforce Register of ARPs

The ACT Asbestos Response Taskforce Register lists the addresses of all ARPs. The ACT Asbestos Response Taskforce, has agreed to make this list available to the research team for this study to identify the ‘exposed’ group.^k

Medicare data

Medicare data will be used to identify exposed and non-exposed cohort members, requiring full historical address information of all ACT residents listed on the register. This will be used to link with ACT Asbestos Response Taskforce Register to identify all persons who have ever lived at an address on the register and their approximate period of residence. In addition, full name, sex and

^kNote that the ACT Asbestos Response Taskforce is likely to make this list available to the general public, on or around 30 June 2015.

date of birth will be required for the purposes of then linking to the National Death Index and Australian Cancer Database.^l

The Australian Cancer Database (ACD)

The ACD is a data collection of all primary malignant cancers diagnosed in Australia since 1982. The ACD is compiled at the AIHW from cancer data provided by state and territory cancer registries through the Australasian Association of Cancer Registries. Standard data items in the ACD are listed in Appendix 10. Linkage with the ACD will follow standard AIHW methods using full name, sex, date of birth and, where possible, address. Only standard items will be required by the researchers for the analysis of the data, including: date of diagnosis, International Classification of Diseases (ICD-10) code, state/territory of usual residence at diagnosis,^m postcode at diagnosis, date of death and cause of death. Further information on the ACD is available at: <http://www.aihw.gov.au/australian-cancer-database>.

The National Death Index (NDI)

The NDI is a database, housed at the AIHW, which contains records of all deaths occurring in Australia since 1980.ⁿ These data are provided by the Registries of Births, Deaths and Marriages, the Australian Bureau of Statistics and the National Coroners Information System. Request to access these data is made directly to the AIHW. (Further information on the NDI, including data request procedures, can be found at: <http://www.aihw.gov.au/national-death-index/>). For this study, data required includes full name, sex, date of birth and address (for data linkage) and date of death and cause of death (for the analysis).

Data linkage (integration)

Formal guidelines for integrating Commonwealth data for research projects have been established by the National Statistical Service. A map outlining the process is shown in Appendix 11, with full details, including how to apply for access to Medicare data for research purposes, available on the Australian Government National Statistical service website (<http://statistical-data-integration.govspace.gov.au/>).

The Data Integration Services Centre at the AIHW, which is a Commonwealth-accredited data integration authority, will be the appointed authority for this project. They will facilitate access

^l We are awaiting further information from the AIHW Data Integration Services Centre regarding how the Medicare registration data are organised and the quality of these data.

^m In order to report the number and proportion of ACT residents with a cancer diagnosis whose diagnosis was reported in another state.

ⁿ The AIHW has recently been granted access to the latest cause of death unit record files, up to 2012 and are expected to have 2013 data by the time the study commences. 2012 and 2013 will not be final but this is mostly due to uncompleted Coroner cases, this is unlikely to have a large effect on cancer deaths.

to the data, link the Medicare, cancer, death and ACT Asbestos Response Taskforce register data, and provide secure storage of the data.

Data will be linked probabilistically based on relevant variables in the various datasets, including full name, sex, date of birth and address, as described above. Importantly, a separation principle is in place. The separation principle means that no one working with the data can view both the linking (identifying) information (such as name, address, date of birth or ABN) together with the merged analysis (content) data (such as clinical information, benefit details or company profits) in an integrated dataset. (See Appendix 12).

More details on the linkage process, particularly around data access and security, can be found in Section 7.7 under 'Secure data management'.

Study variables

Outcomes. The primary outcome is a diagnosis of mesothelioma, as identified by the ICD code in the ACD (ICD-10-AM code C45). Secondary outcomes will also be identified through ICD codes, and will include lung (C34), ovarian (C56), laryngeal (C32), pharyngeal (C10-C14), stomach (C16) and colorectal (C18-C21) cancer. We will also examine deaths from mesothelioma, ascertained through the NDI.

Exposure status. The primary exposure—having lived at an ARP—will be ascertained by linking addresses in the Medicare database with the ACT Asbestos Response Taskforce register of ARPs. Exposure will be treated as a binary variable (exposed/unexposed), where a person is classified as exposed if any of their addresses in the Medicare database match an address in the Taskforce register of ARPs at any time in the study period (i.e. at any time from 1984 to 2014). Note that duration, not just fact, of exposure is of interest; however, because the Medicare data are left-truncated (i.e. there are no data before 1984) there is no way of estimating total duration of exposure in this study, hence the choice of a binary exposure as the main exposure variable for this study. However, in order to allow for appropriate calculation of cancer rates during the follow-up period, and to perform analyses around timing of exposure, variables will also be created with the start and end dates of exposure, i.e. of when the person was registered as residing at an ARP and when they were not, during the study period.

Other variables (potential confounders). Sociodemographic variables to be included in the analyses include: age, sex and area-level socioeconomic status. Area-level socioeconomic status will be based on the Socio-Economic Indexes for Areas (SEIFA) Index of Relative Socioeconomic Disadvantage (IRSD) [10] derived from postcode of residence, and categorised into quintiles using cut-off scores from the Australian census. For participants entering the cohort in 1984, the 1986 version will be used, and for subsequent entrants, the versions of the SEIFA (1991, 1996, 2001, 2006 and 2011) that best aligns to the year of entry will be used. Smoking exposure, another

potential confounder, will be estimated, using published estimates for the ACT general population (from the ABS Australian Health Survey and the ACT General Health Survey) and estimates for those of ARPs from the ACT Asbestos Health Survey (Study Component 3).

7.6. Data analysis

Exclusions: While everyone registered as residing in the ACT up to 2014 is captured in this study, anyone with a potential follow-up period of <10 years (i.e. those first registered as living in the ACT after 2004) will be excluded from the analyses to allow for a minimum plausible latency period (i.e. time between exposure and development of mesothelioma). Sensitivity analyses will also be performed using a range of minimum potential follow-up periods.

For each outcome (i.e. mesothelioma, mesothelioma deaths and each of the other nominated cancers), crude incidence and mortality rates will be calculated for the exposed (those who have lived at an ARP) and the unexposed.

Poisson regression will be used to model the relationship between exposure and each of the outcomes, adjusting for age and sex. Prior to the modelling procedure, we will use indirect standardisation to calculate the expected cases. For Objective 2, expected cases will be based on observed cases among ACT residents of non-ARPs (by age, sex and period^o); however, it may be that small numbers may mean it is not possible to do this analysis for all outcomes. For Objective 3, we will use age-sex-period specific observed cases for Australia (excluding ACT and WA) as the standard (see Component 1 for details on this method and relevant data sources). The observed and expected cases will then be used in the regression analysis. Assuming cases are Poisson distributed, we will regress observed cases on exposure using a log link, with the log of expected cases as an offset. Where there is sufficient power, further adjustment will be made for socioeconomic status and smoking in the analyses.

All analyses will be performed using Stata version 13 (StataCorp).

Power calculations

The exposed cohort is comparatively small, limiting the power to detect significant effect sizes (relative rates) for uncommon cancers, including mesothelioma. For power calculations we have made the following assumptions: (a) 10,000 individuals have lived in the ARPs at any time during the period 1982–2014; (b) the expected number of events among the residents is 2% of the ACT events. Based on the fact that there were 22 incident cases of mesothelioma in the ACT for the period 2002–2006, [11] suggests that the expected number of cases among the exposed in five years will be approximately $22 \times 0.02 = 0.44$. Assuming a Poisson distribution, with 5% significance

^o This may be single year, or aggregated over several years, depending on numbers of cases

and 80% power and a null hypothesis of 0.44, we can detect a significant change with 3 cases in the exposed, for a rate ratio of 6.8. For 20 years of follow-up, with an expected count of $22 \times 0.02 \times 4 = 1.76$ cases, then we could detect a significant change with 5 cases among the exposed, for a rate ratio of 2.8. The power to detect significant relative risks for other cancers, particularly lung cancer, will be substantially higher.

7.7. Ethical issues

Ethics applications

While the AIHW acts as a custodian of state and territory registry data for the purposes of producing national cancer statistics, cancer registries retain ownership of their jurisdiction's data at all times. Thus, multiple ethics and data custodian approvals are required, from the different jurisdictions, as well as from the institutions involved in the research. Ethics approvals will be sought from:

1. ANU Human Research Ethics Committee
2. AIHW Ethics Committee
3. ACT Human Research Ethics Committee
4. NSW Population and Health Services Research Ethics Committee
5. SA Health Human Research Ethics Committee
6. Human Research Ethics Committee (Tasmania) Network
7. Cancer Council Victoria Human Research Ethics Committee
8. WA Department of Health Human Research Ethics Committee^p
9. The Commonwealth Department of Health Ethics Committee

Data custodian approvals will be sought from the Department of Health for use of Medicare data, and state and territories as required for cancer data.

Privacy and waiver of consent issues

The study is compliant with all Australian Privacy Principles (APP) except APP6 (use or disclosure of personal information). As this project is to be conducted without consent, which would breach APP6, a waiver of consent pursuant to section 95 of the Privacy Act 1988 will be sought on the basis of the large number of people involved and the lack of current address information for most of them.

Secure data management

The study team will adhere to strict guidelines to ensure security of data. Individual-level identifying information, required to link data, will be performed by the AIHW, a Commonwealth-

^p Note institutional ethics committee approvals are sufficient to access QLD and NT data.

accredited data integration authority. Details on the accreditation criteria, which have been fulfilled by the AIHW, can be found on the Australian Government National Statistical Service website:

<http://nss.gov.au/nss/home.nsf/pages/Data%20Integration%20-%20AIHW%20accreditation%20application%20and%20audit%20summary/#CIV>

Only de-identified data will be available to the researchers at the ANU who will be carrying out the analyses. These data will be made available through the Secure Unified Research Environment (SURE). SURE is a high-powered computing environment, which is a remote-access data research laboratory for analysing routinely collected health data. It allows researchers to log in remotely and securely to analyse data from sources such as cancer registries and death registries. SURE was developed by the Sax Institute, as part of the Population Health Research Network. SURE is accessed via AARNET (the Australian Academic and Research Network) or the internet using an encrypted connection from researchers' local computers, which must meet security requirements. All users must complete training on privacy, ethics, information security and statistical disclosure control and sign a deed that sets out the terms and conditions for using SURE. Further details can be found at: <https://www.saxinstitute.org.au/our-work/sure/>.

7.8. Potential additional study: Nested case-control study

As mentioned earlier (Section 7.3), the feasibility of a nested case-control study is yet to be established. Key feasibility issues that need to be addressed relate to availability of data, the time and costs involved in performing this study, and the power to detect significant results. The benefit of performing this additional study is that it would provide more detailed information on exposure, in both cases and non-cases of mesothelioma, potentially providing more accurate assessment of risks.

For this study, cases could include all cases of mesothelioma reported to the ACT Cancer Registry between 1984 and 2014, with controls selected from the study population described above, i.e. from people on the Medicare Register who were ever registered as living in the ACT between 1984 and 2014. Multiple controls would be selected for each case, matching on age, sex and postcode. For each case and control, details would be collected on their residential history, including whether the participant was ever registered as living:

- a. in an ARP (address identified in Medicare data),
- b. near an ARP (address identified in Medicare data),
- c. in a house that has had renovations /remediation work carried out (data obtained through ACT Planning and Land Authority).

Exposure could be categorised into one of four categories: ARP renovated, ARP not renovated, not ARP renovated, not ARP not renovated. Logistic regression or modified Mantel-Haenzel could be used to model the relationship between exposure and mesothelioma.

The major problem with this study is likely to be the lack of power. Ideally, this study would also link to electoral records to ascertain exposure prior to 1984 (given the age of diagnosis, the electoral role is likely to capture the exposure history for vast majority of cases and age-matched controls). However, the feasibility of this proposal is highly uncertain as the Australian Electoral Commission does not usually under-take data-matching.⁹ Nevertheless, we are exploring the possibility that this may be undertaken by an accredited data integration authority, if the appropriate APP 6 waiver is granted.

8. Quality assurance, monitoring & safety

NCEPH is proactive and responsible in its approach to risk management. The Research Office within the College of Medicine Biology and the Environment oversees all population health research within ANU. The Research Office oversees the application of research proposals and financial accountability for the conduct of research. The ANU has human and animal research ethics committees that function in accordance with National Health and Medical Research guidance. The Research Office ensures that all funded research is approved by the appropriate ethics committee and complies with University policies.

The study will have ethics approval and oversight from the Human Research Ethics Committees of both ACT Health and the ANU and any other interstate committees as required. The ACT Health Human Research Ethics Committee will be considered the primary committee for all applications. These Committees will ensure that research is conducted according to the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research. All members of the NCEPH team will submit statements supporting that they have read and understood the NHMRC statement.

The ACT Asbestos Health Study will be overseen by a Steering committee comprising representatives from the ACT Asbestos Response Taskforce, ACT Health, NCEPH and the NSW

⁹ There is no power in the Electoral Act (or relevant Privacy legislation) for data-matching action to be undertaken by the AEC. Subsections 90B(5) and (7) of the Electoral Act specifically limit what information the AEC can lawfully disclose for the purposes of medical research so that it can only be an age range (of at least 2 years) and is unable to include the actual date of birth information of electors for the purposes of medical research. It is doubtful that the AEC may lawfully undertake data-matching under the Electoral Act. Proposals lodged with a HREC for such access must address APP 6 as the AEC is being asked to use the information in the Roll for a purpose other than that for which it was collected. See: http://www.aec.gov.au/Enrolling_to_vote/About_Electoral_Roll/medical_research.htm

Chief Health Officer, and other academic experts as required. This committee will ensure that the study is of high quality and meets proposed timelines.

9. Finance and resource use

The study is being funded by the ACT Government (contract ref number: KH626309).

10. Dissemination of results and publication policy

The results of each component of the ACT Asbestos Health Study will be detailed in a report for ACT Health and the ACT Asbestos Health Study Steering Committee. The study team will also prepare manuscripts for publication in appropriate peer-review journals, which the Steering Committee will review prior to submission. The leader of each component of the study will take responsibility for drafting the report and manuscript, which will be circulated to study team members. The report and manuscript will acknowledge input and comments provided by the Steering Committee and other experts. Authorship of peer reviewed articles will be determined in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals produced and endorsed by the International Committee of Medical Journal Editors, specifically those considerations set out under heading IIA 'Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship'.

Results will be summarised in a format suitable for lay-people. The form and timing of the communication will be determined by the Steering Committee. The ACT Asbestos Response Taskforce will disseminate this summary. Results may also be published in ACT Government reports.

Findings will be communicated to national and international media through a coordinated media release between the Australian National University, the ACT Asbestos Response Taskforce and ACT Health.

11. Status of these protocols

The protocols in this report represent the ACT Asbestos Health Study team plans and may not reflect final study protocols. Study conduct may change over time depending on various factors, such as feasibility, availability of data, ethical requirements, and the availability of new information.

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13. Appendices

13.1. Appendix 1 – Component 1: ACT Cancer Registry Dictionary

Variable information¹

Variable	Description/Notes	Codes
Age at diagnosis (years)		
Sex		1 – Male 2 – Female
Country of Birth		Codes are according to the Standard Australian Classification of Countries (SACC) issued by the Australian Bureau of Statistics – see link below
AHS of residence at diagnosis	Area Health Service of residence at diagnosis	All records are Australian Capital Territory
Postcode of residence at diagnosis		4 digit Australia Post code with preceding zeros.
SSLA of residence at diagnosis	State and Statistical Local Area of residence at diagnosis	Codes are according to the Australian Standard Geographical Classification (ASGC) issued by the Australian Bureau of Statistics – see link below
Date of diagnosis	The month and year in which the diagnosis was made	MMYYYY
Cancer type	The type of cancer according to the reporting categories for cancer	Coded using International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM)

Variable	Description/Notes	Codes
ICD-0-3 Topography Code	The site of the cancer	Coded according to the WHO International Classification of Diseases for Oncology (third edition) – see link below
ICD-0-3 Morphology Code	Morphology codes are only recorded for malignant neoplasms and insitu breast and melanoma cases	Coded according to the WHO International Classification of Diseases for Oncology (third edition) – see link below
Best Basis of Diagnosis		0 – Cytology including FNA, smears, washing, sputum 1 – Clinical/imaging/biochemical 2 – Histopathology performed 3 – Confirmed by post mortem (obsolete code) 4 – Found at post mortem 5 – Death certificate only 6 – Histopathology sighted at CCR
Degree of spread		1 – Localised to tissue of origin 2 – Regional spread – adjacent organs and/or regional lymph nodes 3 – Distant metastases 9 – Unknown **OTHER** - Invalid data
Thickness of melanomas	Thickness of skin melanomas in mm	
Size of breast cancer	Size in mm	
Date of death	The month and year of death for persons diagnosed with cancer who have since died	MMYYYY
ICD-0-3 Cause of death	The cause of death according to the reporting categories for causes of death (for cancer deaths only)	Cancer deaths coded according to the WHO International Classification of Diseases for Oncology (third edition) – see link below.

Useful links:

Country of birth: <http://www.abs.gov.au/ausstats/abs@.nsf/mf/1269.0>

State and Statistical Local Area: <http://www.abs.gov.au/ausstats/abs@.nsf/mf/1216.0>

WHO International Classification of Diseases for Oncology: <http://www.who.int/classifications/icd/adaptations/oncology/en/>

¹Table adapted from table in 'ACT Cancer Registry [ACT Government, Health Directorate]'; available at <<http://www.cherel.org.au/data-dictionaries>>.

13.2. Appendix 2 – Component 1: Data Request Form ACT Health

ACT Health use only: Request ID Number: Date 02/03/15

DATA REQUEST FORM

ACT HEALTH

This form should accompany any request for data from ACT Health. Requestors should discuss their data needs with the appropriate ACT Health data custodian(s) before completing this form.

1. Requestor's details

Name	Dr Rosemary Korda
Organisation	National Centre for Epidemiology and Population Health, ANU
Position in Organisation	Fellow
Phone/Fax Numbers	(p)02 6125 5583 (f)02 6125 0740
Email	Rosemary.Korda@anu.edu.au

2. Summary and purpose of data request

Please outline the reason(s) for and details of your request and the purpose of your study:

The study team will use data from the ACT Cancer Registry to conduct a descriptive analysis of mesothelioma cases reported in the territory since 1982. Cases will be described according to age, sex, location and year of diagnosis. The analysis will an analysis of trends over time in both incidence and mortality, and a comparison of the observed to the expected number of cases and deaths, using national mesothelioma data as the reference. The ACT Cancer Registry data will also be linked to the ACT Asbestos Response Taskforce register of affected houses (i.e. those houses known to have been insulated with Mr Fluffy insulation) to determine the number of cases resident in an affected houses at time of cancer diagnosis.

3. Dataset(s) required

If you know which dataset(s) will be required for your research, please specify:

ACT Cancer Registry

4. Years required

Please specify which year(s) you require:

1982-last available year of data

5. Type of data required

- | | | |
|---|---|-----------------------------|
| A) Tabulations/summary data | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| B) Unit record files (de-identified) | YES <input checked="" type="checkbox"/> | NO <input type="checkbox"/> |
| C) Unit record files (identified, for record linkage) | YES <input checked="" type="checkbox"/> * | NO <input type="checkbox"/> |
| D) Other type of data (please specify below): | YES <input type="checkbox"/> | NO <input type="checkbox"/> |

* Please note: identified unit records are required to match addresses from the Cancer Registry to those in the ACT Asbestos Response Taskforce register of affected houses, which will be performed by designated ACT Health staff. However, only de-identified unit record files are required by the research team at ANU for this project. See 'Data Details' for further information. The ACT Health Human Research Ethics Committee has approved this project (Referred to as 'Component 1, Descriptive Analysis'). Copies of the HREC application and approval letter are attached in the accompanying email.

Data Details

If you know which variables will be required for your research, please specify (for summary data/tables, please also advise which cross-tabulations you may require):

We require unit record files for all records with a cancer type code of C45 (mesothelioma), We require the following variables:

- Age at diagnosis (years)
- Sex
- Country of Birth
- AHS of residence at diagnosis
- Postcode of residence at diagnosis
- SSLA of residence at diagnosis
- Date of diagnosis
- Cancer type
- ICD-0-3 Topography Code
- ICD-0-3 Morphology Code
- Best Basis of Diagnosis
- Degree of spread
- Date of death
- ICD-0-3 Cause of death
- Residence status*

* Residence status is a customised project-specific variable. Specifically, the ANU research team are requesting a binary variable, coded as 1 if the case was resident in an affected house at the time of diagnosis and 0 otherwise. To create this variable, ACT Health requires access to addresses of affected houses, held by the ACT Asbestos Response Taskforce. In the Asbestos Health Study Steering Committee meeting on 05/02/2015, head of the Taskforce, Mr Andrew Kefford, agreed to release the residential addresses to the relevant ACT Health staff for this purpose.

Note the relevant section in ACT Human Ethics application, p.8:

The ACT Cancer Registry data will also be linked to a list of Affected Residential Premises addresses to determine the number and proportion of cases resident in an Affected Residential Premises at the time of cancer diagnosis.

6. ACT Human Research Ethics Committee approval

Due to concerns over privacy and confidentiality regarding access to unit record data, or summary data which may yield small cell sizes (less than 5) or relate to small/sensitive populations, ACT Health recommends that requestors seeking access to this type of data first lodge an application for approval with the ACT HREC.

a) Have you submitted an ethics application? YES (Go to Question 7b)

NO (Go to Question 8)

b) Do you have ACT HREC approval? YES NO IN PROGRESS

If you have submitted an ethics application, please attach it to this request form, along with any response you received from the ACT HREC. (Attached to accompanying email.)

7. Additional Information/Comments

If you have additional information or comments relevant to your data request, please include these here:

The following ACT Health staff are collaborators on this project: Elizabeth Chalker, Leah Newman, Hai Phung (Epidemiology Branch).

Signature of Applicant

Date of application

02/03/2015



Please note that for access to some data, such as the ACT Cancer Registry, you may need to supply additional documentation. This may be for security reasons or due to the legislation covering the data. An ACT Health data custodian will contact you after processing your initial request and provide the relevant form(s) for you to complete in order to fulfil this requirement.

13.3. Appendix 3 – Component 1: ANU Ethics Submission

HUMAN RESEARCH ETHICS COMMITTEE

Application Form

Created by: **u2557724**

Record number: **7144**

Protocol type: Expedited Ethical Review (E1)

Protocol number: **2014/808**

Date entered: **18/12/2014**

Ethics program type: **Staff**

Requested start date: **16/02/2015**

Requested end date: **31/12/2017**

Protocol title: ACT Asbestos Health Study - Component 1 Descriptive analysis of mesothelioma cases in the Australian Capital Territory

Investigators

Name	Role	Department
Banwell, Cathy	Co-investigator	Natl Centre for Epidemiology & Population Health, CMBE Research School of Population Health, ANU
Kirk, Martyn	Primary investigator	Natl Centre for Epidemiology & Population Health, CMBE Research School of Population Health, ANU

Name	Role	Department
Korda, Rosemary	Co-investigator	Natl Centre for Epidemiology & Population Health, CMBE Research School of Population Health, ANU

Investigators Detailed

Name: Banwell, Cathy **Role:** Co-investigator

Expertise: Associate Professor Cathy Banwell, Dip T BA MA PhD, has qualifications in arts (anthropology), teaching and a PhD in community medicine. She is a qualitative researcher at the National Centre for Epidemiology and Population Health and is the Delegated Authority for higher degree research students at the Research School of Population Health.

Areas of expertise: Associate Professor Banwells research focuses on socio-cultural research contributions to public health. She has extensive expertise in qualitative research and she has conducted various research studies into health issues, including cultural issues in Thailand, illicit drugs and alcohol, socio-cultural contributors to obesity and time and health inequalities.

Associate Professor Banwell has extensive expertise in qualitative research methods, having spent her career conducting qualitative research on highly sensitive health topics such as alcohol and illicit drug use.

Name: Kirk, Martyn **Role:** Primary investigator

Expertise: Associate Professor Kirk, BAppSci MAppEpid PhD, is currently the Head of the Master of Philosophy in Applied Epidemiology program, Australias Field Epidemiology Training Program, at the National Centre for Epidemiology and Population Health based at the Australian National University. He

has qualifications in applied science, applied epidemiology and a PhD in infectious disease epidemiology. Associate Professor Kirks research primarily focuses on the epidemiology of food and water borne diseases and he has extensive experience in investigating outbreaks and clusters of human diseases.

Associate Professor Kirk has expertise in undertaking disease surveillance and leading outbreak investigations, including investigating intoxications due to environmental contaminants, such as bromine, copper and cyanobacterial compounds. He has investigated more than 100 disease outbreaks including Legionnaires' disease, cholera, trematode infections, salmonellosis, shigellosis, and Campylobacter infections. Associate Professor Kirk has experience in working collaboratively to achieve research goals; has successfully lead collaborative research projects; has an in-depth understanding of outbreak and cluster investigations; and has expertise in data collection and analysis, and interpretation and dissemination of study results.

Associate Professor Kirk has been involved in setting up surveillance networks for investigating foodborne diseases in Australia and has conducted large cross sectional surveys that have been published as government reports and in the peer review literature. This includes reports for the Commonwealth Department of Health on the incidence of gastroenteritis in Australia and on foodborne illness in Australia.

Name: Korda, Rosemary **Role:** Co-investigator

Expertise: Dr Rosemary Korda, BAppSc MAppSc GradDipPopHlth PhD, has qualifications in applied science, population health and a PhD in epidemiology. She is a Research Fellow in epidemiology at the National Centre for Epidemiology and Population Health and is the Deputy Head of the Chronic Disease Epidemiology Group. Areas of expertise: Dr Korda has expertise in chronic disease and health services research. She has experience in managing research projects and in the design and analysis of studies involving large-scale health data. She has detailed knowledge of epidemiological methods, particularly those related to prospective cohort studies using data linkage, and has expertise in health economics.

Dr Korda has extensive experience in analysing linked administrative health data, including hospital, cancer registry, mortality, medication benefits scheme and pharmaceutical benefits scheme data, resulting in 10 published studies using these data.

External Investigators

Name	Role	Institution
Armstrong, Bruce K	Co-investigator	University of Sydney
Chalker, Elizabeth	Co-investigator	Commonwealth Department of Health and Ageing ^f
Clements, MS	Co-investigator	Karolinska Institutet
Newman, Leah	Co-investigator	ACT Government Health Directorate

External Investigators Detailed

Name: Armstrong, Bruce K **Role:** Co-investigator

Expertise: Professor Bruce Armstrong, AM, FAA, BMedSc (Hons), MBBS (Hons), DPhil (Oxon), FRACP, FAFPHM, has qualifications in medicine and public health including a PhD in epidemiology. He is an Emeritus Professor at the School of Public Health, The University of Sydney and is a Fellow of the Royal Australasian College of Physicians and a Fellow of the Faculty of Public Health Medicine of the Royal Australasian College of Physicians. Professor Armstrong has several awards including an award for lifetime contributions in basic science to the field of melanoma and was awarded Member of the Order of Australia in 1998.

Areas of expertise: Professor Armstrong is an internationally recognised expert on the epidemiology of mesothelioma and other environmentally-mediated cancers. His research has made major contributions to our understanding of the epidemiology and aetiology of melanoma, melanocytic naevi and non-

^f Elizabeth Chalker works for ACT Government Health Directorate

melanocytic skin cancer and the consequences of exposure to crocidolite asbestos. Professor Armstrong has worked on asbestos-related diseases for over 30 years.

Professor Armstrong has wide ranging expertise in analysis of linked health data on including on the epidemiology of mesothelioma and other environmentally-mediated cancers.

Name: Chalker, Elizabeth **Role:** Co-investigator

Expertise: Ms Chalker, BSc GradDipCompStud, has extensive experience in the analysis of health related data. She is currently the Manager of the ACT Cancer Registry and a Senior Officer within ACT Health. In this role, Ms Chalker has undertaken several descriptive analyses of cancer data. She also worked at the National Centre for Epidemiology and Population Health, ANU, for many years undertaking descriptive and more complex statistical analyses of health data sets. She has co-authored several publications in national and international journals. Ms Newman and Ms Chalker recently undertook a similar analysis to the one proposed in this application for ACT Health.

Name: Clements, MS **Role:** Co-investigator

Expertise: Associate Professor Mark Clements has qualifications in science including a PhD in epidemiology, biostatistics and mathematical modelling. Associate Professor Clements is a University Lecturer in the Department of Medical Epidemiology and Biostatistics at the Karolinska Institutet in Sweden.

Areas of expertise: Associate Professor Clements is a highly regarded biostatistician with expertise in cancer modelling, including asbestos related diseases. He has expertise in biostatistics and quantitative methods with previous work in research on cancer rate projections, models for lung carcinogenesis and mesothelioma projections.

Associate Professor Clements is an experienced biostatistician who has an extensive track record in analysing linked data, developing methods for cancer rate projections and developing cancer models.

Name: Newman, Leah **Role:** Co-investigator

Expertise: Ms Newman, BA (Hons) MClinEpid, has extensive experience in the analysis of health related data particularly with the collection and analysis of cancer data. She is currently the Population Health Informatics Manager for ACT Health under which the ACT Cancer Registry sits. She has also had many years of experience collecting and analysing data for the Tasmanian Cancer Registry and the Menzies Research Institute including descriptive analyses of cancer data. She has contributed to publications in national and international journals. Ms Newman and Ms Chalker recently undertook a similar analysis to the one proposed in this application for ACT Health.

Departments

Primary	Department	Faculty
Yes	Natl Centre for Epidemiology & Population Health	CMBE Research School of Population Health

Project Questions Detailed

Description of Project

Describe the research project in terms easily understood by a lay reader, using simple and non-technical language. The ACT Asbestos Health Study will investigate the potential health effects of living in a residence known to have been insulated with Mr Fluffy insulation in the Australian Capital Territory (ACT) (hereafter referred to as an affected residence). The study comprises four discrete parts: (1) a descriptive analysis of mesothelioma cases, (2) focus groups of health concerns, (3) a cross sectional survey of residents, and (4) a data linkage study examining potential risk from living in an affected residence. These component parts will be completed over a 2-year period between Jan 2015 and Dec 2017.

This HREC application seeks ethical approval for the first component of the study:

(1) Descriptive analysis of mesothelioma cases in the Australian Capital Territory.

Location of Data Collection

Australia Yes

Overseas No

Provide country / area where data collection will be conducted ACT, Australia

Aims of the Project

List the hypothesis and objectives of your research project. The objective of this study is to describe the incidence of diagnosed mesothelioma in ACT residents in relation to demographic factors, and to compare ACT incidence rates to national incidence rates. The study will also examine whether people diagnosed with mesothelioma in the ACT were living in an affected residence at the time of diagnosis.

The key research questions are:

1. What is the distribution of mesothelioma in the Australian Capital Territory in relation to key sociodemographic factors, including age, sex and year of diagnosis?
2. How do mesothelioma incidence rates compare to those for the rest of Australia?
3. What number and proportion of cases were living in an affected residence at the time of diagnosis?

Methodology

In language appropriate for a lay reader, explain why the methodological approach minimises the risk to participants. (For surveys, include justification of the sample size). The study team will conduct a descriptive epidemiological study of mesothelioma cases reported in the ACT since 1982. The study methods in this proposal have been developed in discussion with ACT Health. They use existing data (i.e. no new data are being collected for this study). The data include: (1) standard de-identified data from the ACT Cancer Registry; (2) an additional ACT Health custom-created variable (yes, no) to identify whether or not the case was in an affected residence at the time of diagnosis; this variable will be created by ACT Health, with data supplied by the ACT Asbestos Response Taskforce (<http://www.act.gov.au/asbestos-response-taskforce>); and (3) published data on mesothelioma cases in Australia, from the Australian Institute of Health and Welfare.

The incidence of mesothelioma will be described according to age, sex, location (Statistical Local Area of residence at diagnosis), year of diagnosis, and whether in affected residence at the time. The analysis will include: (1) comparison of age-standardised mesothelioma incidence and mortality rates over time, separately in men and women; (2) comparison between the observed and the expected number of cases and deaths, using published national mesothelioma data as the reference; and (3) a cumulative map comparing densities of affected residences and cases.

We believe that potential risks of this study are minimal. The descriptive study will be conducted in a way to minimise possible breaches in privacy and confidentiality. No personal identifying information, such as names, addresses or dates of birth, will be available to the ANU researchers who are analysing the data for this study, and none of these details will be reported. Data will be stored on a secure server at the ANU.

Provide the survey method, a list of the questions to be asked or an indicative sample of questions. These should give a good sense of the most intrusive/sensitive areas of questioning. Not applicable

What mechanisms do the researchers intend to implement to monitor the conduct and progress of the research project? For example:

How often will the researcher be in touch with the supervisor?

Is data collection going as expected? If not, what will the researcher do?

Is the recruitment process effective?

How will the researcher monitor participants willingness to continue participation in the research project, particularly when the research is ongoing? The project was commissioned by ACT Health and has gained ethics approval from ACT Health. All investigators on the project have signed Confidentiality Deeds with ACT Health.

The ACT Asbestos Health Study will be overseen by a Steering committee comprised of key stakeholders from the the Chief Health Officer, ACT Health;; Head of the ACT Asbestos Response Taskforce; Contract manager and representative of the Health Improvement Branch, ACT Health; the National Centre for Epidemiology and Population Health Study Leaders; and the NSW Chief Health Officer representative (Director of Environmental Health) and other academic experts as required. This committee will ensure that the study is high quality and meets proposed timelines. The steering committee will meet at least once every two months.

Participants

Provide details in relation to the potential participant pool, including:

target participant group;

identification of potential participants;

initial contact method, and

recruitment method. The descriptive study is based only on existing data (ACT Cancer Registry) and already published data from the Australian Bureau of Statistics and the Australian Institute Of Health and Welfare, so involves no recruitment of study participants.

Proposed number of participants 0

Provide details as to why these participants have been chosen?

Cultural and Social Considerations/Sensitivities

What cultural and/or social considerations/sensitivities are relevant to the participants in this research project? The subject matter of this study is sensitive due to the current situation in the Australian Capital Territory, that is, the highly-publicised issues around potential exposure to asbestos associated with living in a Mr Fluffy house and the potential health consequences. The situation is currently ongoing and will likely continue to be sensitive for the next 4-5 years. All data analyses, publication of results and communications will be overseen by an ACT Government steering committee.

Incentives

Will participants be paid or any incentives offered? If so, provide justification and details. No

Benefits

What are the anticipated benefits of the research? Greater understanding of: patterns of diagnosed mesothelioma in ACT residents in relation to demographic factors; how incidence rates compare to those elsewhere in Australia; and whether mesothelioma cases were resident in an affected residence at the time of diagnosis.

This study is one component part of a larger study that will provide insight into the epidemiology and health effects of asbestos-related disease in the Canberra region.

This study is one component part of a larger study that will provide insight into the epidemiology and health effects of asbestos-related disease in the Canberra region.

To whom will the benefits flow? The key beneficiaries of this, and related studies, are: current and past residents of affected residences, the general and scientific communities, and the ACT Government.

Informed Consent

Indicate how informed consent will be obtained from participants. At least one of the following boxes **MUST** be ticked 'Yes'.

In writing No

Return of survey or questionnaire No

Orally No

Other Yes

If Oral Consent or Other, provide details. Cancer diagnosis is notifiable under law and so no consent is obtained from cases to submit their diagnosis to the Cancer Registry. The research team will submit a request to the ACT Cancer registry for the release of de-identified unit record files for this project, which is allowable under the current ACT Health data release policy, subject to appropriate ethics clearance. Ethics approval has been obtained from ACT Health Human Research Ethics Committee.

Confidentiality

Describe the procedures that will be adopted to ensure confidentiality during the collection phase and in the publication of results. Confidentiality will be maintained at all times for this study. All research staff will sign a Confidentiality Deed supplied by the Territory. All data will be stored on access-protected

files on a secure ANU server. Only named investigators who have signed a Confidentiality Deed with ACT Health will have access to these files.

Data Storage Procedures

Provide an overview of the data storage procedures for the research. Include security measures and duration of storage. Information will only be accessible to approved project staff in access-protected folders at the Australian National University until 30 Dec 2017. Thereafter, information will be stored on secure servers by ACT Health for 7 years and may be destroyed at that time. If it is not destroyed at this time, storage will remain on secure servers at ACT Health until they are destroyed.

Feedback

Provide details of how the results of the research will be reported / disseminated, including the appropriate provision of results to participants. If appropriate, provide details of any planned debriefing of participants. The results will be disseminated to the study participants and the ACT community. The form and timing of the communication will be determined by the research steering committee. Results will also be published in ACT Government reports and in peer reviewed journals.

Supporting Documentation

Please ensure electronic copies of any supporting documentation have been uploaded the documents tab of the relevant protocol.

Has this work been approved by another Human Research Ethics Committee (HREC)? Yes

If yes, please give the name of the approving HREC. ACT Health HREC

Funding

Is this research supported by external funding? Yes

Provide the name/s of the external sources of funding. Please include grant number/s if available. ACT Government contract ref number: KH626309

Is the research conducted under the terms of a contract of consultancy agreement between the ANU and the funding source? Yes

Describe all the contractual rights of the funding source that relate to the ethical consideration of the research. The Territory owns the contracted material and the IP rights. The ANU retains background IP and materials. The Territory retains background IP and materials.

The Territory will be involved in all aspects of the design of the project and has a royalty-free, perpetual license to reproduce, adapt, publish and communicate the produced material.

ANU has agreed to request consent from the Territory before publishing any contracted material, not publish any personal information and will acknowledge contributions made by the Territory in all publications. ANU will ensure safe-keeping and appropriate preservation of the contract and Territory material.

The Territory is able to request amendments or delays in publication (if amendments are impractical) if it is deemed that a proposed publication discloses confidential or sensitive information.

Expedited Questions Summary

Question	Answer
Third Party Identification	No
Children or Young People	No
Dependent or Unequal Relationship	No
Membership of a Group, or Related Issues	No
Physical Harm	No
Psychological Harm (includes Devaluation of Personal Worth)	No
Social Harm	No
Economic Harm	No
Legal Harm	No
Covert Observation	No
Deception	No
Sensitive Personal Information	No
Overseas Research	No
Collection, use or disclosure of personal information WITHOUT the consent of the participant	No

Clinical Trials

Criteria for Inclusion .

Criteria for Exclusion .

Has a risk assessment been undertaken by the proposer? No

If yes, give details of the assessment process .

Give details of sponsor's insurance .

Could this work cause damage to the university's reputation No

If yes, please give details .

Does your Clinical Trial involve a drug or device? No

The trial must be registered with the Australian New Zealand Clinical Trials Registry, has this been done?
No

If yes, state the name of the Registry .

If yes, state the Registration number .

If no, state the reasons why trial registration has not been undertaken .

If your clinical trial involves a DRUG OR DEVICE, you will need to provide a copy of your protocol (with attachments) to the Insurance Office. Please contact the Insurance Office on extension 54257 or insurance.office@anu.edu.au for further information.

Supporting Documentation

Please ensure electronic copies of the supporting documentation have been uploaded into the documents tab of your protocol.

These may include (please circle the relevant answer):

List of indicative questions Y/N

Copy of questionnaire / survey Y/N

Invitation or introductory letter/s Y/N

Publicity material (posters etc.) Y/N

Information sheet Y/N

Consent form Y/N

External approval documentation Y/N

Research visa (if applicable) Y/N

Other (specify below) Y/N

For other, please specify:

SIGNATURES AND UNDERTAKINGS

PROPOSER OF THE RESEARCH

I certify that all the persons listed in this protocol have been fully briefed on appropriate procedures and in particular that they have read and are familiar with the national guidelines issued by the National Health and Medical Research Council (the National Statement on Ethical Conduct in Human Research 2007).

I certify that the above is as accurate a description of my research proposal as possible and that the research will be conducted in accordance with the National Statement on Ethical Conduct in Human Research 2007. I also agree to adhere to the conditions of approval stipulated by the ANU Human Research Ethics Committee (HREC) and will cooperate with HREC monitoring requirements. I agree to notify the Committee in writing immediately of any significant departures from this protocol and will not continue the research if ethical approval is withdrawn and will comply with any special conditions required by the HREC.

Signed:..... Date:.....

ANU SUPERVISOR

I certify that I shall provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above:

Signed: N/A..... Date:.....

AS FROM MONDAY 21ST OCTOBER 2013 THE SIGNATURE OF THE HEAD OF ANU DEPARTMENT/GROUP/CENTRE IS NO LONGER REQUIRED.

13.4. Appendix 4 – Component 1: Waiver of Consent Request



ACT Health

Health Human Research Ethics Committee

WAIVER OF CONSENT REQUEST

Study Title	ACT Asbestos Health Study Part 1: Descriptive study of mesothelioma cases in the ACT
Contact Person	Ms Kanupriya Kalia Hehir
Department Include building and level	National Centre for Epidemiology and Population Health Research School of Population Health Building 62 The Australian National University Acton 2601 AUSTRALIA
Email	Kanupriya.Kalia.Hehir@anu.edu.au
Phone/Mobile	02 6125 3053

This waiver of consent request is submitted in conjunction with the above titled research project. The criteria for addressing waiver of consent requests, as set out by the National Statement on Ethical Conduct in Human Research (2007), Chapter 2.3.6 are addressed below.

- (a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

This study is considered low risk to study participants, as it is a descriptive analysis of secondary data from the ACT Cancer Registry that will not involve any contact with study participants or their families.

- (b) (b) the benefits from the research justify any risks of harm associated with not seeking consent

The study into the distribution of mesothelioma in the Australian Capital Territory is necessary to allow assessment of the risk of developing mesothelioma compared to the general Australian population. As the research is considered low risk, the benefits in terms of improved understanding of the epidemiology of this disease outweigh the potential risks.

- (c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

The study will analyse reports of mesothelioma to the ACT—many of whom will have died making it impractical to obtain consent. In the 2013 report on mesothelioma in Australia, the Australian Mesothelioma Registry reports that 37.9% (218/575) cases diagnosed with mesothelioma in 2013 died (http://www.act.gov.au/_data/assets/pdf_file/0005/633245/AMR-3rd-data-report-final.pdf). In addition, as this descriptive analysis involves data going back to 1994 since data collection began in the ACT, it is likely that next of kin will have moved as well, as most cases of mesothelioma are older at the time of diagnosis.

- (d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

Given the current public interest in asbestos-related diseases and mesothelioma incidence, there is no reason to think that participants would not have consented to the descriptive study if they had been asked. The study will involve no contact with study participants and only presents results in an aggregated form that will not identify individuals.

- (e) there is sufficient protection of their privacy

In this descriptive study, only aggregated results will be presented in a way to avoid identification of individuals, including suppression of cells with small numbers of cases (in line with the ACT Health Data Release Policy).

- (f) there is an adequate plan to protect the confidentiality of data

The analysis will protect individual's privacy and confidentiality, as data will be stored on a secure server at the ANU and will only be accessible to study investigators. Information will only be accessible to approved project staff in access-protected folders at the Australian National University until 30 June 2017. Only named investigators will have access to these files. All research staff will sign a Confidentiality Deed supplied by the Territory. Thereafter, will Information will be stored on secure servers by ACT Health for 7 years and may be destroyed at that time. If it is not destroyed at this time storage will remain on secure servers at ACT Health until they are destroyed.

- (g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

The results of this descriptive analysis are unlikely to have significance for the participants' welfare, particularly since many participants will have died by the time the data are obtained and analysed. The ACT Government will make a summary of the report available, as the results of the study will be of interest to the ACT community. The form and timing of the communication will be determined by the

research steering committee. Results will also be published in ACT Government reports and in peer reviewed journals.

- (h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

There are no potential for financial benefits for study participants from the analysis of these descriptive data. The results will be reported back to the ACT government in the form of a report and to the scientific community in a peer-reviewed journal publication.

- (i) the waiver is not prohibited by State, federal, or international law

The waiver of consent for this descriptive study of mesothelioma incidence in the ACT is not prohibited by ACT Health, federal or international law.

13.5. Appendix 5 – Component 2: Invitation letter

ACT Asbestos Health Study: Focus Group Discussions

Dear Resident,

The National Centre Epidemiology and Population Health at the Australian National University is conducting a study funded by the ACT Government, on the health and other effects of living in a Mr Fluffy house. As part of this study we are conducting focus group discussions to gather the views of residents.

Your address has been selected at random by us from the list of affected houses provided to us by the Asbestos Response Taskforce. It is important to the overall study that we invite participants who are likely to have had a range of different experiences with their Mr Fluffy houses. We are writing to invite one person from your household to participate in a focus group discussion. This could either be you or another adult household member; this invitation cannot be passed on to a person who was not a resident of this household.

Information about focus group discussions:

We will hold two focus group discussions about your health-related experiences of living in a Mr Fluffy house. This is part of a larger study investigating the risks of living in a Mr Fluffy house. One focus group will be held on the northside and a similar one will be held on the southside. The discussions are likely to take between one and two hours. The venues and further details will be disclosed to those who agree to participate.

When: The focus group discussions will be within the next few weeks. Please notify us of your willingness to participate at your earliest convenience so we may advise you of the venue and date.

What are the focus group discussions about?

The discussion will cover the following topics related to living in a Mr Fluffy home:

- Health concerns
- Risk perception and management related to asbestos exposure
- Stress related to financial and other concerns due to circumstances related to living in an affected residence
- Social issues
- Practical issues — where to live, moving, schooling, work, replacement of belongings, rebuilding house — time costs, other barriers
- The response to the Mr Fluffy situation by government, media, other
- Other issues you or other participants raise.

What we will do after the group discussions:

The discussion material will be audio-recorded if permission is given, collated and analysed. The results of the analysis will contribute to the development of the questions to be used in a later survey sent to current and past residents of Mr Fluffy Houses. The de-identified findings from the study as a whole will be disseminated to participants, to the general public, and published in academic papers. You will not be identifiable in any of these outputs. Raw data will be safely stored on an ANU password protected computer for 5 years and then destroyed.

Are there any risks if you participate?

Your privacy is important to us. We ask that pseudonyms be used in the discussion and that participants refrain from supplying any identifying information during discussions. We will not identify you in research findings. We will not discuss with other people whether you participate or not. Your participation is voluntary and will not affect your position at work, or your use of any ACT Government service. There are no consequences of non-participation. You are free to withdraw from the discussion at any time and you can choose not to engage in discussion about any question that you perceive to be sensitive. It is possible that transcripts from the focus group discussions may be subpoenaed as part of legal actions related to Mr Fluffy litigations. However, transcripts will be de-identified. We ask that all discussion within the focus group remain confidential.

This is an opportunity for you to discuss issues related to living in a Mr Fluffy home and to shape the direction of the next phase of our research (the survey). We sincerely hope that you or another household member will join us.

Yours sincerely,

Cathy Banwell

To register your interest in participating or to seek further information please contact us by email or phone.

Ms Susan Trevenar	T: (02) 6125 6079	Susan.Trevenar@anu.edu.au
Dr Ginny Sargent	T: (02) 6125 5616	Ginny.Sargent@anu.edu.au
Dr Cathy Banwell	T: (02) 6125 0016	Cathy.Banwell@anu.edu.au

Concerns or complaints

The Australian National University and ACT Government Health Directorate Human Research Ethics Committees have approved the ethical conduct of this research (ANU HREC protocol 2015/209, ACT Health Ethics Committee ETH.11.14.330). If you have concerns regarding the way this research was conducted please contact either of the following:

Human Research Ethics Officer

Manager - Human Research Ethics

The Australian National University

ACT Health Directorate Research Office

Office of Research Integrity

Building 10 Level 6

Chancelry 10B, Lower Ground Floor

Canberra Hospital

T: (02) 6125 3427

T: (02) 6174 7968

E: Human.Ethics.Officer@anu.edu.au

E: acthealth-hrec@act.gov.au

13.6. Appendix 6 – Component 2: Consent form

Participant Written Consent Form

ACT Asbestos Health Study

I have read and understood the Information Sheet you have given me about the research project, and I have had any questions and concerns about the project addressed to my satisfaction.

I have been informed that:

- The discussion will relate to health concerns of living in a Mr Fluffy House as detailed on the information sheet
- That I am free to withdraw at any time, that participation is voluntary and that there are no consequences for non-participation
- That all discussions are completely confidential
- That my data will be stored on ANU computers for 5 years and then destroyed
- That transcripts of the discussions may be subpoenaed if there were to be legal actions related to Mr Fluffy litigations.

I agree to participate in the project:

YES NO

I agree to this focus group discussion being audio-recorded:

YES NO

I agree that all discussions with the focus group are confidential

I (please sign) consent to take part in this research project.

Date

13.7. Appendix 7 – Component 2: Questionnaire

ACT Asbestos Health Study
Questionnaire for Focus Group participants

1. Sex Male Female
2. Age _____ (in years)
3. Are you of Aboriginal or Torres Strait Islander heritage?
- No Yes, Aboriginal
- Yes, Torres Strait Islander Yes, both Aboriginal and Torres Strait Islander
4. Which language do you mainly speak at home?
- English Other – Please specify the language: _____
5. What is your highest completed level of education?
- Incomplete secondary Completed secondary
- Certificate or diploma Bachelor degree or above
6. Partnership status
- Single (Never Married) Single (Divorced/ Widowed) Married
- Cohabiting/De Facto
7. What is your employment status?
- Not employed Employed (casual) Employed (part-time)
- Employed (full-time) Student

8. Do you have any children living with you?

Yes No (if No, got to Q10)

9. If you have children living with you, what are their ages?

10. How many people (including children) lived in the Mr Fluffy house with you?

11. How long did you live in the Mr Fluffy house?

12. Did you own or rent the Mr Fluffy house?

Own Rent

13.8. Appendix 8 – Component 3: Invitation letter

ACT Asbestos Health Survey

Dear Resident,

The National Centre Epidemiology and Population Health at the Australian National University is conducting a study funded by the ACT Government, on the health and other effects of living in a Mr Fluffy house. As part of this study we are conducting a survey to determine health-related concerns and likely levels of exposure to asbestos insulation.

I am writing to invite you to complete the online survey (alternatively, you can complete the survey during a telephone interview, please contact the research team to arrange for this, contact details are below).

Information about the survey:

The survey will be open for completion from X October 2015 to XXXX. All ‘current and recent’ members of affected households (who are aged 18 years and over) can participate. If there are several members of your household who are aged 18 or over you are all eligible to participate, it is important that we collect separate information from household members as everybody will have different health related information and exposure through renovation information to provide. It will take approximately 20 minutes to complete the survey.

What is the survey about?

The survey will collect a range of information, including:

- Demographics (age, sex, Indigenous status, marital status, country of birth, language spoken at home, educational attainment, occupation, number of residents in household)
- Whether you own or rent the Mr Fluffy house
- Amount of time at the address
- Who lives/lived in the house
- Exposure to asbestos through renovation work
- Smoking status
- Health concerns
- Level of distress experienced
- Possible financial impact
- Perception of dissemination of health information by ACT Government

- Whether you are willing to provide Asbestos test results for the house to the study team
- Whether you are happy to be contacted in the future for further health studies relating to living in a Mr Fluffy house.

Are there any risks if you participate?

Your privacy is important to us. No identifying information will be collected for the survey. If you agree to take part in further research we will ask for your name, date of birth and contact details, however, we will not save those details with the survey data that is collected. All reported information will be summarised so individuals cannot be identified.

We will not be discussing whether or not you participated with other people. Only members of the research team will have access to the data. The survey is entirely voluntary and there are no consequences for non-participation. The information you provide will not be linked to a name or phone number. The information you provide as part of this survey will be stored securely on ANU servers for five years and then destroyed unless you consent to future studies.

This is an opportunity for you to inform us about the impact of living in a Mr Fluffy house, as well as possible exposure to asbestos. The information collected will be used to examine levels of exposure to loose-fill asbestos and health concerns for residents of these houses.

On behalf of the study team, I sincerely hope that you and all eligible household members will complete the online survey.

Yours sincerely,

Martyn Kirk

For further information please contact us by email or phone.

Dr Martyn Kirk

Ms Sue Trevenar

T: (02) 6125 5609

T: (02) 6125 6079

E: Martyn.Kirk@anu.edu.au

E: Susan.Trevenar@anu.edu.au

Concerns or complaints

The Australian National University and ACT Government Health Directorate Human Research Ethics Committees have approved the ethical conduct of this research (ANU HREC protocol 2015/xxx, ACT Health Ethics Committee ETH.xx.15.xxx). If you have concerns regarding the way this research was conducted please contact either of the following:

Human Research Ethics Officer

Manager - Human Research Ethics

The Australian National University

ACT Health Directorate Research Office

Office of Research Integrity

Building 10 Level 6

Chancelry 10B, Lower Ground Floor

Canberra Hospital

T: (02) 6125 3427

T: (02) 6174 7968

E: Human.Ethics.Officer@anu.edu.au

E: acthealth-hrec@act.gov.au

13.9. Appendix 9 – Component 3: Variable information

Section	Question no.	Variable	Description/Notes	Codes
Respondent	1	Household ID	Unique identifier for household sent out with introductory letter	
	2	House residents*	Number of adults living in the house	Numeric; 0–12
			Number of children age 5-17 living in the house	Numeric; 0–12
			Number of children up to age 4 living in the house	Numeric; 0–12
	3	Main carer	Ask respondent if they are the main carer of the children	Y/N/U [If yes, respondent would be asked marked questions on behalf of each child]
	4*	Respondent age	Age of respondent in years	Numeric; 0–120
	5*	Respondent sex	Sex of respondent	1–Male 2–Female
	6	Marital status	Marital status of respondent	1–Married 2–in de facto relationship 3–single 4–other (specify)
	7	Country of Birth	Country of birth for respondent	Codes are according to the Standard Australian Classification of Countries (SACC) issued by the Australian Bureau of Statistics (: http://www.abs.gov.au/ausstats/abs@.nsf/mf/1269.0)
	8	Aboriginal	Aboriginal/Torres Strait Islander	1–No 2–Yes, Aboriginal 3–Yes, Torres Strait Islander 4–Yes, both Aboriginal and Torres Strait Islander
	9	Language	Which language do you speak mainly at home	1–English 4–Other (specify)
10	School	What is the highest level of schooling you have completed?	1–Year 12 or equivalent 2–Year 11 or equivalent 3–Year 10 or equivalent 4–Completed primary school 5–Did not complete primary school 6–Did not go to school	
11	Highest Education	What is the highest educational qualification you have completed outside of school?	1–Doctorate 2–Masters Degree 3–Graduate Diploma 4–Graduate Certificate 5– Bachelor Degree 6–Advanced Diploma or Associate Degree	

Section	Question no.	Variable	Description/Notes	Codes
Household	12	Employment	Employment status	7–Diploma 8–Certificate IV 9–Certificate III 10–Certificate II 11–Certificate 1 12–No post-school qualifications 1–Unemployed 2–Employed (casual) 3–Employed (part-time) 4–Employed (full-time) 5–Retired 6–Student
	13	Occupation	Occupation of respondent	Free-text
	14	Work activities	What activities do you do at work?	Free-text
	15	Industry	What industry do you work in?	Free-text
	16	Income	Household weekly income	1–Negative income 2–Nil income 3–\$1-\$199 (\$1-\$10,399) 4–\$200-\$299 (\$10,400-\$15,599) 5–\$300-\$399 (\$15,600-\$20,799) 6–\$400-\$599 (\$20,800-\$31,199) 7–\$600-\$799 (\$31,200-\$41,599) 8–\$800-\$999 (\$41,600-\$51,999) 9–\$1,000-\$1,249 (\$52,000-\$64,999) 10–\$1,250-\$1,499 (\$65,000-\$77,999) 11–\$1,500-\$1,999 (\$78,000-\$103,999) 12–\$2,000 or more (\$104,000 or more) 98–Don't know
	17	First moved to house*	Year and month of when the respondent and their family first moved into the affected premises	Month & Year
	18	When left house*	Year and month when respondent and family left the affected premises	Month & Year
	19	Owner*	Question asking if they were the owner of the house	1–joint owner of the house with partner 2–sole owner of the house 3–rental 4–other (specify)

Section	Question no.	Variable	Description/Notes	Codes
	20	First aware*	When respondent first new that they were living in an 'affected premises'	Month & Year
	21	Results of tests*	Respondent to indicate where asbestos was found on testing	1–bedrooms (specify whose bedroom) 2–main living area 3–kitchen 4–living room 5–bathrooms 6–other (specify)
	22	Renovations*	Have you had any renovations done?	Y/N/U
	Q23 to Q33 repeated for each renovation/room			
	23	Year begun	Respondent to specify the year of renovation	Start year for each renovation
	24	Length of time	Length of time for this renovation	Duration (days/weeks/months) for each renovation
	25	Room renovated	Which room was renovated?	1–Living area 2–Kitchen 3–Bathroom 4–Bedroom 5–Other (specify)
	26	Living in house	Did the respondent and family live in the house while the renovations were underway? (Filter for subsequent renovation questions)	Y/N/U
	27	Self renovations	Did the respondent do any of the renovation themselves?	Y/N/U
	28	Asbestos contact	Did the respondent have any contact with asbestos insulation?	Y/N/U
	29	Dust protection	Did the respondent take any respiratory precautions (dust/mist mask) during renovations?	Y/N/U
	30	Estimated time	Respondent to estimate the total amount of time that	Numeric (hours or days)

Section	Question no.	Variable	Description/Notes	Codes
Wellbeing & health issues	31	Roof space	they spent in contact with asbestos insulation Did the respondent ever enter the roof space of the 'affected premises'?	Y/N/U
	32	Roof space frequency	How frequently did the respondent enter the roof space	1–Never 2–Once 3–2-3 times 4–4-10 times 5–more than 10 times
	36	Estimated time2	Respondent to estimate the total amount of time that they spent in the roof space	Numeric (hours or days)
	34	Under floor	Did the respondent ever enter the space under the floor?	Y/N/U
	35	Under floor frequency	How frequently did the respondent enter the space under the floor	1–Never 2–Once 3–2-3 times 4–4-10 times 5–more than 10 times
	36	Estimated time3	Respondent to estimate the total amount of time that they spent in the space under the floor	Numeric (hours or days)
	37	Other contact	Respondent to mention any other relevant contact with asbestos insulation	Free text field
	38	Known contact	Respondent to mention any other contact with asbestos through occupation	Free text field
	33	Health	Ask respondent about 'self-rated health'	Scale from 1—Excellent through to 5—Poor
	40	Specific problems	Have you experiences specific asbestos related health problems	Free text field
	41	First reaction	Describe first reaction of finding out that the house was an 'affected premises'	Scale from 1– extreme distress through to 5–no concerns
	42	Anxiety	DQ-5 Ask the respondent about their level of worry and anxiety in the past 30 days	Scale 1–5 for a. Overwhelming worry b. Hopeless c. Upset by social settings

Section	Question no.	Variable	Description/Notes	Codes
	43	Feelings	K6 Ask respondent how they feel in the past 30 days	d. Trouble focusing e. Anxiety or fear interfered with normal tasks Scale 1–5 for a. nervous b. hopeless c. restless or fidgety d. depressed e. that everything was an effort f. worthless
	44	Problems	PHQ-2 Ask the respondent whether they were bothered in the last 2 weeks, including lack of interest, and feeling down GAD-2 Same introduction for question above about: feeling nervous and uncontrollable worry	Scale from 1—not at all or 3—nearly every day Scale from 1—not at all or 3—nearly every day
	Q45 repeated for each child			
	45	Children's concerns**	Ask the respondent if their child had experienced any worry about living in an affected premises	Scale from 1—not at all through to 5—extremely worried
	46	Financial concerns	Ask respondent about how worried they are about finances as a result of asbestos in their home	Scale from 1—not at all through to 5—extremely worried
	47	Social concerns	Ask respondent about how worried they are about social issues as a result of asbestos in their home	Scale from 1—not at all through to 5—extremely worried
	48	Concerns about mesothelioma	Ask respondent about how worried they are about developing mesothelioma in the future?	Scale from 1—not at all through to 5—extremely worried
	49	Concerns about other health issues	Ask respondent about how worried they are about developing other health problems in the future?	Scale from 1—not at all through to 5—extremely worried
	50	Current smoking	Ask respondent if they smoke on daily basis.	Scale from 1—daily through to 3—not at all (See: http://www.who.int/tobacco/surveillance/en_tfi_tqs.pdf)

Section	Question no.	Variable	Description/Notes	Codes
Comments & general information	51	Past daily smoking	Ask respondent if they smoked daily in the past	Y/N/U
	52	Past smoking	Ask respondent smoking status in the past	Scale from 1—daily through to 3—not at all
	53	Type of tobacco	Ask respondent about type of tobacco smoked and quantity	a. Manufactured cigarettes b. Hand-rolled cigarettes c. Kreteks d. Pipes full of tobacco e. Cigars, cheroots or cigarillos f. Pipes full of tobacco g. Any others (specify)
	54	Smoking in house	Ask respondent if anyone smokes inside the home	1—Daily 2—Weekly 3—Monthly 4—Less than monthly 5—Never 6—Don't know
	55	Provide test results	Ask respondents if they are willing to provide results of independent asbestos testing	Y/N/U [If yes, specify results and request that they email a scanned copy of results to the ACT Asbestos Health Study team]
	56 57–63	General comments Further research	Any general comments Ask respondent if they are willing to participate in future health research relating to asbestos	Free text Y/N/U [If yes, collect name, date of birth, Medicare number, mobile phone number, email and contact details of a close relative]

*—Questions administered to primary respondent only

**—Questions asked of main carer about each child living in the house.

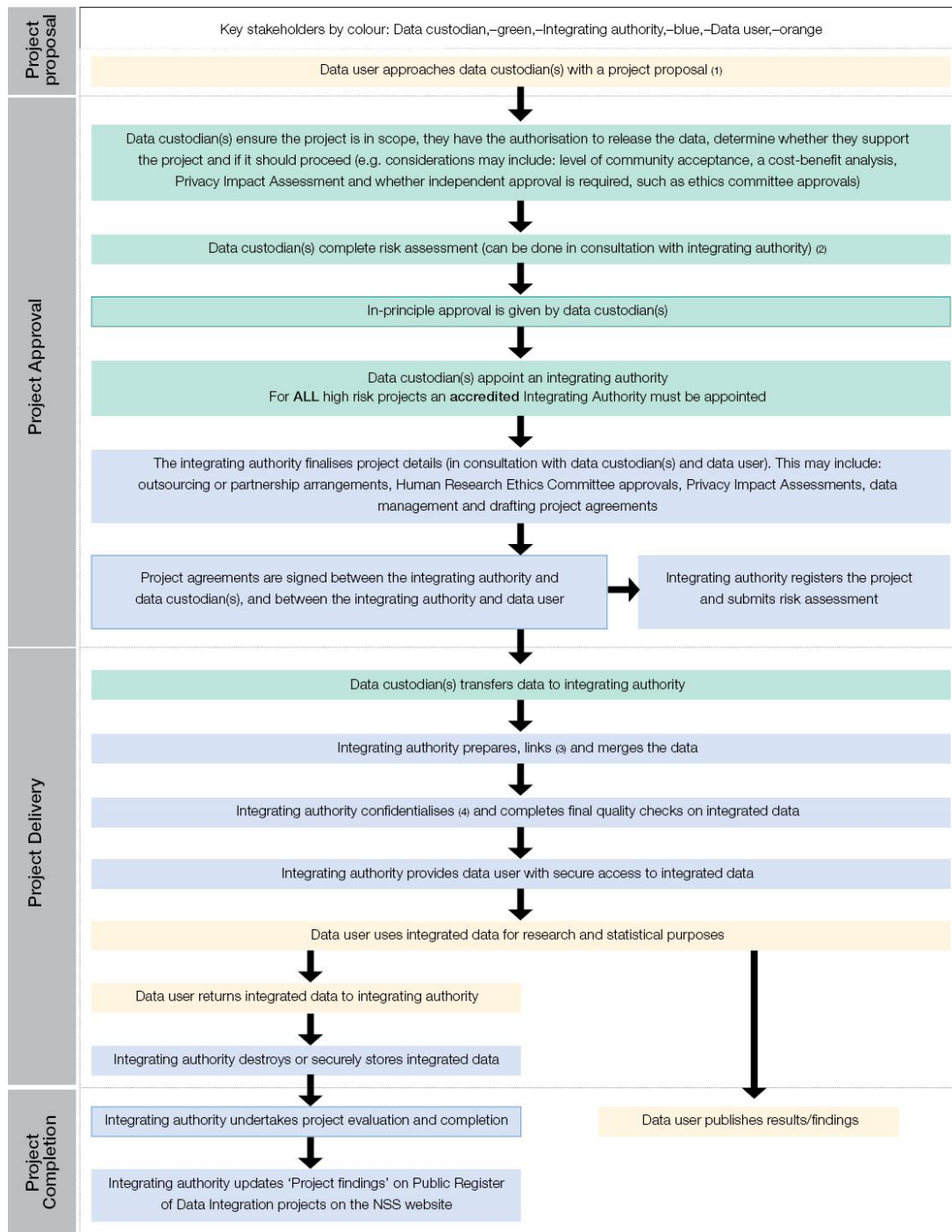
13.10. Appendix 10 – Component 4: Australian Cancer Database: Standard data items

Australian Cancer Database agreed minimum data set	
Person-level attributes	Tumour-level attributes
Person identification number (assigned by the state/territory)	State/territory of usual residence at diagnosis
Surname	Tumour identification number (assigned by the state/territory)
First given name	Date of diagnosis
Second given name	Date of diagnosis accuracy indicator
Third given name	Age at diagnosis
Sex	ICD-O-3 ^(a) topography code
Date of birth	ICD-O-3 ^(a) morphology code
Date of birth accuracy indicator	ICD-10 ^(b) disease code
Indigenous status	Most valid basis of diagnosis
Country of birth	Statistical local area at diagnosis
Date of death	Postcode at diagnosis
Age at death	Melanoma thickness (Breslow)
Cause of death	Tumour size (breast cancer only)

Source: <http://www.aihw.gov.au/australian-cancer-database/>

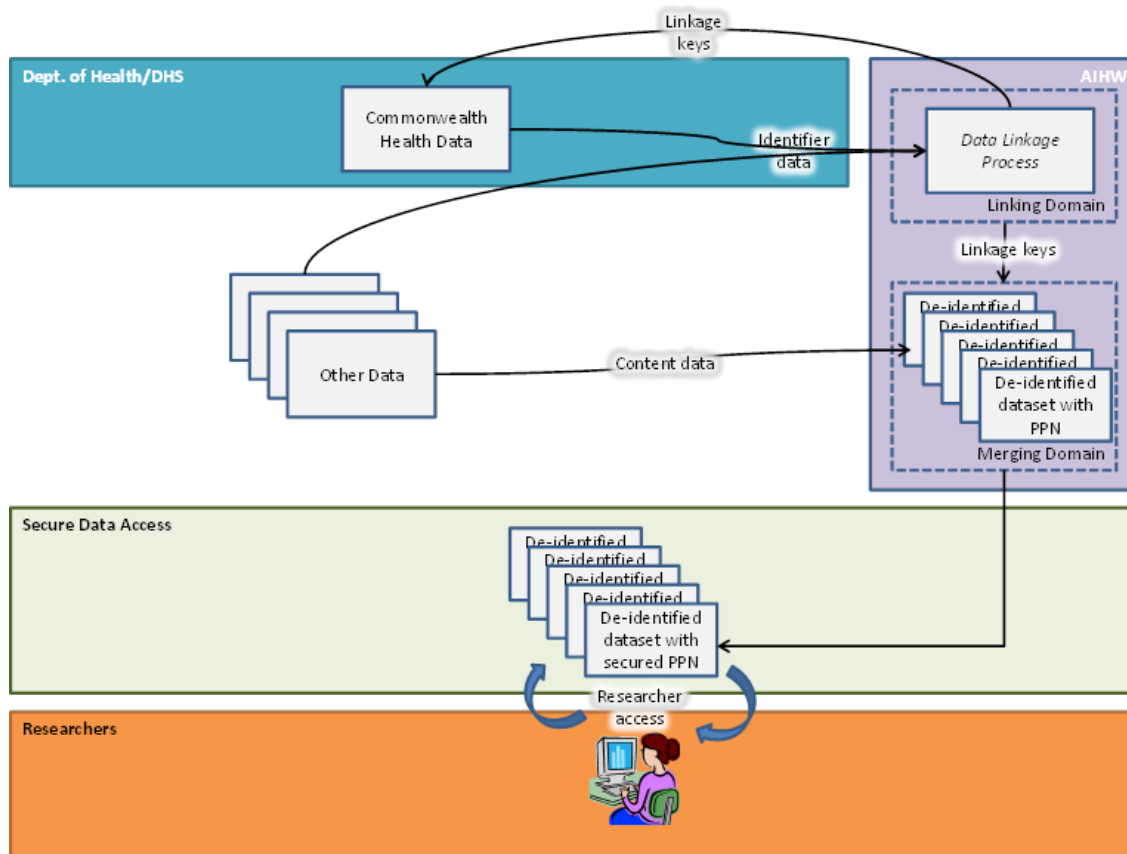
13.11. Appendix 11 – Component 4: Data linkage process

A Process Map for Data Integration Projects



Source: National Statistical Service: <http://statistical-data-integration.govspace.gov.au>

13.12. Appendix 12 – Component 4: Data separation process



Source: Australian Institute of Health and Welfare: <http://www.aihw.gov.au>