AIR QUALITY AND RESPIRATORY HEALTH STUDY

The Lane Cove Tunnel Health Investigation

Protocol

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1. TITLE OF THE STUDY

Air Quality and Respiratory Health Study-
The Lane Cove Tunnel Health Investigation

2. PURPOSE OF THE STUDY

2.1 Background

There is widespread community concern about health effects due to air pollution. There has been a long history of research into the short-term health effects of specific air pollutants. Effects on risk of death, hospitalisation, respiratory symptoms, lung function and various biomarkers have been described. More recently research has focused specifically on health effects attributable to exposure to traffic-related air pollution. Similar outcomes have been studied.

There is consensus among scientists working in this field that the inhalation of fine particles and irritative and/or oxidant gases, some of which arise from vehicular traffic, does have measurable effects on health. However, the quantitative relationships between exposure to pollutants and health outcomes remain very uncertain. Extension of these data to allow quantitative assessment of the effect of vehicular traffic on health is even more problematic. The potential confounding effects of other exposures and sociodemographic factors impose some limitation on the interpretation of cross-sectional studies that have directly examined the relation between exposure to vehicular traffic and health.

Experimental designs in which subjects are studied under conditions of high and low vehicular traffic exposure would address some of these limitations but data from such studies are very scarce in the published literature. Hence, it is difficult, based on current evidence, to provide confident advice about the likely impact of interventions which may change local communities' exposure to road traffic related air pollution.

Over the past two decades, transport strategies for the Sydney metropolitan area have included the construction of an orbital network of motorways around the city (M1, M2, M7, M5, Airport Expressway) and also the enhancement of existing travel routes by motorway construction (eg M5 from the Airport to Liverpool, M2 from Artarmon to the north west). Some of these motorways have required construction of “missing links” of roadworks. The Lane Cove Tunnel, which will link the M2 with the Gore Hill freeway, the M5E East Tunnel linking the M5 with the Airport, and the Cross-City Tunnel are examples of such projects. Further tunnels are planned for other roadways currently under consideration by the RTA. In Sydney, there is some community acceptance that road tunnel infrastructure will alleviate congestion on surface roads, allowing for faster travel times. However, there is sustained community concern over the ventilation of road tunnels through ventilation stacks, as well as the cost involved in payment for the road tolls once commissioned. More recently, community concern has also focussed on the closure of nearby surface roads when road tunnels are opened.

Experience from the M5 East Tunnel

Prior to the Cross-City Tunnel, the last major stack-ventilated road tunnel to be opened in Sydney was the M5 East tunnel. Experience gained from the investigation of possible adverse health effects after that tunnel opened is relevant to the planning of the current investigation.

Planning for the M5 East tunnel indicated that modelled air pollutant concentrations arising from the tunnel operations, including the one ventilation stack, would not lead to a rise in air pollution

levels compared with background levels and would not cause exceedances of air quality standards. Nevertheless, after commissioning of the tunnel, the NSW Health Department received over 80 complaints from residents living in the vicinity of the ventilation stack. Complaints concerned odour, symptoms of eye, nose and throat irritation and respiratory symptoms. Air quality monitoring of the area showed that there had not been any detectable increase in the air pollutants, NO_2 and PM_{10}.

Affected residents were invited to attend a clinic, where their complaints were assessed by a team of respiratory, allergy and occupational physicians. Among the 54 people who attended, 63% had at least one symptom which could plausibly be linked to the ventilation stack emissions. This qualitative investigation was followed by a quantitative, cross-sectional survey in which the prevalence of eye, nose and throat and respiratory symptoms was measured. This revealed no difference in the prevalence of these symptoms between those who were close to the stack and exposed to its emissions and those who were further away. Hence, this study was not able to establish any relationship between the ventilation stack and adverse health outcomes in nearby residents.

There were a number of limitations to this study. First, it was cross-sectional in nature and no health data were collected from residents prior to the opening of the tunnel. Second, data on exposure to tunnel or stack-related air pollutants was limited to allocation to three exposure zones. Finally, no objective respiratory health measurements were made.

The Lane Cove Tunnel (LCT) project provides an opportunity to conduct a more rigorous study to assess the association between traffic related air pollution and respiratory health, with measurements made both before and after the tunnel opens.

The Lane Cove Tunnel

The Lane Cove Tunnel is a 3.6 kilometre 2 to 3 lane carriageway which will link the existing Gore Hill freeway at Artarmon and the M2 motorway at East Ryde. It is expected to reduce the travelling time to the city from the north west sector of Sydney by 15 minutes and to reduce surface road congestion around the Lane Cove area. The Roads & Traffic Authority estimate that the tunnel and road works will be completed in December 2006. The tunnel has been designed to be vented by two ventilation stacks located at either end of the tunnel, the eastern stack in the industrial area at Artarmon near Marsden Road, and the western stack in the Lane Cove West industrial area in Sirius Road.

Air quality modelling conducted by the project builders indicate that under worst case conditions, emissions from the ventilation stacks will contribute very little to background concentrations of NO_2, PM_{10} and $PM_{2.5}$. Air quality is also projected to improve along the major surface roads in the area such as Epping and Mowbray Roads, but is estimated to deteriorate slightly near the feeder roads to the tunnel, although it is not projected to exceed ambient air quality goals.

Community Concerns

The major community concerns related to the Lane Cove Tunnel construction and operation include:

1. the possibility of increases in ground level pollution in areas surrounding the two tunnel ventilation stacks, including both traditional pollutants and odour; and
2. the increases in pollution in areas surrounding the tunnel feeder roads, which will experience higher traffic flows.
3. the narrowing of Epping Road from three lanes to one commuter lane of traffic.

The Lane Cove Tunnel Action Group, a local community advocacy group, along with Lane Cove Council, has advocated for the ventilation stacks to incorporate filtration for the pollutants. Government has not agreed to this proposal due to the modelled projections of no adverse additional pollution arising from the stacks, cost involved, and a lack of agreed or standardised technology to remove gaseous components of the emissions.

Lane Cove Tunnel Health Investigation
The NSW Health Department has supported an epidemiological study to be conducted among residents in the community surrounding the Lane Cove Tunnel to determine whether respiratory health is affected by changes in traffic related air quality in the area. The study is being undertaken by the Woolcock Institute of Medical Research and the CRC for Asthma and Airways and is funded by the CRC and the NSW Health Department.

A series of four studies will be conducted to study respiratory health and related symptoms in the population surrounding the Lane Cove Tunnel before and after the opening of the road tunnel. In one study a cohort of residents living in four distinct areas surrounding the LCT will be assessed by questionnaire. The questionnaire will include questions on respiratory and irritant symptoms, severity of symptoms, use of medication, potential time variable confounding or effect modifying factors, and environmental concern (Questionnaire Survey). The questionnaire will be administered to the study cohort in 2006, before the tunnel opens, and again one year later, after the tunnel opens. A sub-group of these residents will also be recruited into a second study involving the recording of daily peak flow measurements and symptom diaries (Diary Study). Each person recruited into the Diary Study will record measurements for 9 weeks in 2006 and again at the same time of year in 2007. A third study will focus on the potential short-term effects arising from exposure to emissions from the ventilation stacks. Subjects will be "exposed" to ventilation stack emissions, and to control conditions, before and after the opening of the tunnel (Picnic Study). The exposure will comprise gentle walking for two hours and will take place in two locations around the Lane Cove area and in one location at Camperdown where air quality is not expected to change between 2006 and 2007. Outcomes to be assessed during each exposure period include sensory and respiratory symptoms and lung function. The fourth study will measure changes in exposure to nitrogen dioxide (NO_2), a traffic-related air pollutant, using passive samplers. Ambient concentrations of NO_2 will be measured in various locations around the study area to assess spatial variation of NO_2. These measurements will be used in a land based regression model to predict NO_2 levels for all participants in the questionnaire study. The passive samplers will also be used for personal exposure assessment. The overall study aims will be addressed by an analysis of changes in health outcomes in relation to the opening of the tunnel and changes in air pollutant exposure using data from all four studies.

While there are many published studies examining the relation between air pollution levels and health, these studies only provide indirect evidence about the likely impact of changes in pollution, both beneficial and adverse, due to the opening of new motorways, tunnels and ventilation stacks. This study represents a unique opportunity to provide direct evidence of any effect of the changes in air pollution, due to the opening of the tunnel, on the respiratory health of adults residing in the Lane Cove, Ryde and Willoughby areas. Our study will achieve this by using well-validated and objective measures of respiratory health and making measurements before and after the tunnel opens. This will be important for urban planners, government and the general public in New South Wales, as well as nationally and internationally. This is particularly important in New South Wales where future motorway development and tunnels are planned for urban areas.

2.2 Main Aims

The main aims of the study as a whole are:

1. To establish whether changes in air quality occurring between the year before the tunnel opens and the year after the tunnel opens have an influence on community health.

2. To establish whether any changes in community health are specifically attributable to emissions arising from the ventilation stacks.

3. To explore the use of a number of methodologies for assigning exposure to traffic related air pollution.

3. STUDY MANAGEMENT

3.1 Steering Committee

3.1.1. Remit

The *Lane Cove Tunnel Health Investigation Steering Group* has been formed by the NSW Health Department (NSW Health) to provide expert advice to the Chief Health Officer and the Investigators on the design, analysis and interpretation of the health investigation.

3.1.2. Composition

The members of the steering group have been chosen for their specific expertise and their role is to provide advice on the design, implementation, analysis or interpretation of the investigation relating to their field of expertise. Steering group members bring the following areas of expertise to the study:

- Environmental epidemiology
- Air pollution-asthma epidemiology
- Air quality measurement and modelling
- Biostatistics.

The Public Health Unit director for the Northern Sydney Area is a member of the Steering Group. This person has expertise in air pollution and asthma epidemiology as well as being director in public health for the area covered by the study. The community interest is represented by a representative chosen by Lane Cove Council. This representative is an air quality consultant.

3.1.3. Meetings

Meetings will be held twice yearly or more frequently if requested by the Chair or the Chief Investigator. Four of the five members will be considered a quorum. If a member is unavailable for a lengthy period then an alternate member with similar expertise can be included in the quorum. Members may participate remotely via teleconference. The steering group tenure shall be until the completion of the final report. This is anticipated to be June 2008.

3.2 Study Management Group

The health investigation will be managed by the Woolcock Institute of Medical Research (WIMR), on behalf of the CRC for Asthma and Airways. The WIMR will manage and carry out all aspects

of the health investigation in liaison with the Environmental Health Branch of the NSW Health Department and as agreed by the Steering Group.

3.2.1 Team members

The studies will be led by Associate Professor Guy Marks, a specialist respiratory physician with the WIMR. Key staff include Christine Cowie and Adriana Cortes. Research assistants will be employed during the data collection and data entry phase.

3.2.2 Meetings

Meetings will normally be held every Friday to discuss progress of the investigation. Additionally, meetings will be held as the need arises.

4. EXPOSURE ASSESSMENT

4.1 Introduction

Accurate exposure assessment is often a weakness in the conduct of epidemiological studies examining the impact of adverse air quality on health. Most of these studies have relied on existing air quality data collected by environmental agencies for the purpose of studying trends in air quality. Routinely collected air quality data provide very coarse spatial resolution and hence are of limited value for assessing individual exposures. In contrast, there are robust and well validated respiratory health outcome measurements used in epidemiological studies, such as spirometry and exhaled nitric oxide. This study will combine robust health outcome measurements with more detailed exposure measures, by exploring a number of methodologies for predicting individual exposures to traffic-related air pollution. Additional funds have been secured through a grant from the Commonwealth Department of Environment & Heritage's *Clean Air Research Programme* (CARP) to conduct air quality monitoring using passive samplers and for the exposure assessment activities as outlined below.

4.2 Aims of exposure assessment

The aims of the air quality monitoring & exposure assessment are:

1. to develop a range of metrics for assigning individual exposures to traffic related air pollution;
2. to assess the correlation among these traffic-related air pollution exposure metrics and their relation to personal exposure data using NO_2 passive samplers;
3. to determine which of these newly developed traffic-related air pollution metrics is most useful for predicting human health outcomes.

4.3 Methodologies

We will test metrics designed to assess both long-term and short-term exposures. Air pollution exposure metrics to be tested include a number of methodologies based on proximity type assessments (eg distance to main road), land use regression models, interpolation models, and dispersion and emission modelling. These metrics will also be compared to a smaller sample of personal exposure data to determine how the measurements differ.

4.3.1 Existing air monitoring

We will use data from six fixed site monitors that have been located within a small geographic area (approximately 7 km^2) surrounding the LCT by the builders of the tunnel. Two monitors are

located near each of the tunnel ventilation stacks, and four at other locations in the area. The monitoring is a requirement of consent conditions and is being funded by the tunnel proponent. A further air quality monitor is located at Mowbray Public School, Lane Cove West, and has been established by Willoughby City Council. All available data will be sought.

These monitors can provide high resolution data on temporal variation in air quality and some information about spatial variation in the area. They collect data on ambient levels of NO_2, $PM_{2.5}$ and PM_{10}. The CARP proposal will enable modelling of data from these fixed site monitors to estimate individual exposures to NO_2, $PM_{2.5}$ and PM_{10} within the study area (described further below).

4.3.2 Proposed air sampling

Area wide ambient monitoring

We will deploy approximately 40 passive NO_2 samplers within the study area to measure spatial variation in this pollutant. This will occur over 2-3 two week periods in 2006 and again in 2007. CSIRO (partners in the CARP proposal) will supply the passive samplers in the form of sealed vials. These samplers will be installed on site in a location that avoids tampering or impact from rain. Shelters will be used to protect the ambient samples from rain which can affect results; otherwise they will be installed outside participants' homes (vials are 25 mm in diameter). They will be positioned with a velcro strip or suspended by string from the ceilings of verandahs, porches or eaves (or similar) on the house/building. They will be left for a sampling period of two weeks, and then sent to the CSIRO for analysis.

This is further described under 4.3.3 Interpolation Method.

Personal exposure monitoring

We will also conduct some personal exposure monitoring by recruiting a subset of participants in the epidemiological study and other local people to wear passive badge samplers for NO_2. People who participate in the personal sampling program will also be involved in the ambient monitoring program by having passive samplers deployed outside their home. Collection of these data on personal exposures will allow comparisons to be made between ambient and personal sampling. For some personal samples, we will recruit two people living in the same house, which will allow us to see how personal exposures can differ for people living at the same address. Participants will be asked to wear the passive samplers for a seven day period to take into account all activities normally carried out by that person during the week and the weekend.

Passive samplers

The detection limit is 0.5 ppb and the passive samplers have an average precision of 8%. To further assess precision in the field, duplicate samplers will be placed at 20% of the locations. CSIRO Marine and Atmospheric Research's analysis laboratory issues certification for all sample analysis and has recently been assessed for NATA certification. CSIRO is awaiting confirmation of its status.

A pilot run using two samples has been conducted in the area. The ambient sampler was located at the same address as the residence of the personal sampler. The results were:

Ambient sampler: 17.0 ppb (4 days)
Personal sampler: 10.8 ppb (6 days)

4.3.3 Development of exposure metrics

We will develop and test four different metrics for assigning individual exposure to road traffic air pollution. These will be based on the assessments listed below.

CARP funds will be used to purchase relevant datasets (eg traffic volumes, population density), GIS expertise and analysis for the development of the exposure metrics, NO_2 passive samplers and analysis, modelling of pollutants by the CSIRO, analysis of the modelling and interpretation of the data.

Proximity based assessments

These assessments use data such as traffic volume on nearby roads, and distance to nearby roads as predictors for exposure to traffic exhaust. We will access geographic information system (GIS) street layers (or maps) and road traffic data from the relevant agencies and organisations (Land and Property Information, RTA and Local Councils in New South Wales) and use ARC-GIS to estimate distance from main roads and/or other distances.

Land use regression models

This type of model enhances the predictive power of proximity-based models by additionally including data related to land use such as street type, topography, population density and land use type as predictors of exposure to traffic related air pollution. The same GIS software will be used as for the proximity models.

Interpolation method

This method has been used, in conjunction with land use regression models, to improve the accuracy of prediction of specific pollutants (such as NO_2, as a marker of traffic related air pollution) within a defined geographic area. We will use passive samplers to measure ambient NO_2 at 40 sites within a small geographic area to help determine small scale spatial variation of NO_2 in an intraurban context.

Using these data together with topographic and land use data and GIS techniques, we will develop a regression model to estimate NO_2 exposures levels with a fine spatial resolution within the defined area. The model will be constructed to best predict individual exposure to long term average NO_2 (annual average) for adults and children both at their home address as well as at their school address (if local). This road traffic air pollution metric will be used to investigate associations between traffic related air pollution and changes in children's and/or adult's lung-function (described below).

These interpolation-based estimates will be validated against data from the fixed site monitors and emissions-based modelled data (see below). A number of alternative methods for assigning exposure will be assessed in this way.

Dispersion and emission modelling

Dispersion and emission modelling integrating emissions, meteorological and topographical data, will be conducted to estimate individual long-term and short-term exposure to $PM_{2.5}$, PM_{10} and NO_2 for individuals on a long-term and short-term basis. This modelling will be conducted by CSIRO using the TAPM and near road dispersion model (Lagrangian Wall Model (LWM)). TAPM will provide background concentrations for the area surrounding the Lane Cove Tunnel taking into account the effects of meteorology and emissions for the entire Sydney airshed. The results from TAPM will be used to initialise the LWM which in turn will be used to assess the dispersion from roadways within the immediate area at a resolution of 10 metres.

At present the LWM is the only model of its type able to assess the impact of roadways at very high resolution while taking into account the effects of complex atmospheric chemical reactions. It is also the only model available to simultaneously assess the impacts of roadway and tunnel stack emissions. This type of modelling will capture temporal and spatial variation in air quality enabling the investigation of associations between short-term variations in symptoms and short-term changes in air pollution. Modelling can also be used to predict the long-term variation in air quality for these parameters. Both the long and short term outputs from these models will be incorporated as underlying themes within the GIS framework to enable comparison between each of the assessment methods.

The model TAPM has been validated for a number of case studies in urban areas. The LWM system has been validated against the extensive Caltrans 99 (Sacramento) data set and General Motors Sulphate experiments. In addition CSIRO implements comprehensive project management systems to ISO standards for all projects, to ensure delivery to scope, timeline and budget. This proposal will be managed using these guidelines and tools.

4.3.4 Comparison of exposure metrics

We will compare the newly developed traffic related air pollution exposure metrics to determine how well they correlate with each other and to assess their relation to personal exposure data.

We will examine

- the correlation of the dispersion and emissions based modelling with the fixed site monitors (both 24 hr average and annual averages for NO_2, $PM_{2.5}$, PM_{10});
- the correlation of the dispersion and emissions based modelling with the passive NO_2 samplers (2 week averages);
- the correlation of the dispersion and emissions based modelling with the interpolation method, the proximity assessment model, or a combination of the above (annual averages for NO_2);
- the correlation of the fixed ambient air monitor data and the personal exposure data (1 week averages for NO_2);
- the correlation of the passive ambient NO_2 samplers with the personal exposure data (2 week averages of ambient compared with 2x1 week average for personal samplers).

We will also establish which, if any, of these metrics best predicts changes in respiratory health outcomes.

4.4 Assigning exposure

The estimates of exposures (using the various metrics explored above) will be linked with respiratory health outcomes that are measured during the Questionnaire Survey and the Diary Study (see Table 4.1).

Each Questionnaire Survey participant's exposure to pollutants will be estimated for their home address and, where appropriate, for the address of their school. The change in pollutant exposure between 2006 (before the tunnel opens:T1) and 2007 (after the tunnel opens:T2) will be tested as a predictor of changes in health outcomes.

In addition, data on day to day variation in air pollution from fixed site monitors will be used to examine the relation between changes in air pollution and day to day variation in respiratory

symptoms in panels of participants who keep symptom diaries (Diary Study). These will also be used to assess the effect of short term peaks in pollutant exposure levels.

Table 4.1 Linking exposure data to health outcome data

Type of health outcome	Health outcomes	AQ Monitoring outcomes	Source of data: NO_2	Source of data: PM_{10}, $PM_{2.5}$
Medium-long term effects	Mean change in lung function and airway inflammation) T1:T2 (Diary study: spirometry, peak flow, exhaled NO) (individual level)	Change in NO_2 Change in PM_{10}, $PM_{2.5}$ (annual averages)	Fixed site monitors; modelled data; land based regression model metric; interpolated NO_2 metric	Fixed site monitors; modelled data
	Change in severity of symptoms T1:T2 (Q'aire survey & Diary study: individual level)	Change in NO_2 Change in PM_{10}, $PM_{2.5}$ (annual averages)	Fixed site monitors; modelled metric; land based regression model metric; interpolated NO_2 metric	Fixed site monitors; modelled data
Short-term effects	Exacerbation of symptoms (=daily basis) during Diary study data collection period	Daily data for NO_2 and PM_{10}, $PM_{2.5}$ (24 hr averages)	Fixed site monitors, modelled data	Fixed site monitors, modelled data
	Daily changes in peak flow (Diary study)	Daily data for NO_2 and PM_{10}, $PM_{2.5}$ (24 hr averages)	Fixed site monitors, modelled data.	Fixed site monitors, modelled data

5 STUDY AREAS

5.1 Predicted exposures around the LCT

To maximise the likelihood of surveying people who are exposed to the greatest variation in air quality from the Lane Cove Tunnel project, we have chosen study areas based on air quality modelling information presented in the Environmental Impact Statement (EIS). This information is presented in the EIS as air quality contour maps for the pollutants NO_2, PM_{10} and CO. The EIS predicts relatively small changes in annual average air quality for the affected area. For PM_{10} the change (pre-tunnel vs 2016 scenarios) ranges from a 2% improvement to a 2% deterioration on current levels. The predicted changes for NO_2 is greater, with changes ranging from greater than 10% deterioration in some areas up to a 40% improvement in other areas. As the predicted changes in NO_2 are much greater than the predicted changes in PM_{10}, we have used the NO_2 predictions to choose study areas for the Questionnaire Survey and Diary Study as follows:

a) an area at risk of increased exposure to pollution arising from changes in traffic;
(b) an area expected to experience a reduction in traffic-related air pollution; and
(c) a control area, in the same general vicinity but where no change in traffic or pollutant exposure is anticipated;

(d) a further area comprising people living within a 650m radius of the eastern ventilation stack.

The post-hoc validity of this designation of study areas will be assessed after the study by reference to air quality monitoring data available from six fixed site monitors that have been placed in the area surrounding the tunnel and from the passive NO_2 monitoring that will be undertaken.

Exposure will be assigned in a number of ways as indicated in Table 4.1. However, modelling will also incorporate data on short term peaks in exposure for NO_2, $PM_{2.5}$ and PM_{10} for assessing the association with short-term health outcomes.

Annual average exposures will also be assigned to determine their relationship with longer term health outcomes, such as changes in lung function and symptom prevalence.

6 QUESTIONNAIRE & DIARY STUDIES

6.1 Introduction

This investigation will be conducted among members of the local community in the areas described above in 5.1. The prevalence of respiratory symptoms will be measured by questionnaire, in the same subjects, before and after the opening of the tunnel. The change between the pre-tunnel and post-tunnel assessment will be measured for each location in the vicinity of the tunnel and compared with the change in the control area.

6.2 Aims of the Questionnaire & Diary Studies

The major aim of the investigation is to determine whether changes in air quality arising from the opening of the Lane Cove Tunnel, including use of the surrounding feeder roads and ventilation stack emissions, are associated with changes in respiratory health of adults and children living in the study areas.

More specific aims are to test for evidence of:

(a) an increase in adverse health outcomes among people at risk of increased exposure to pollution arising from vehicular traffic, and

(b) a decrease in adverse health outcomes among people living in the area expected to experience a reduction in traffic-related air pollution.

The health outcomes of specific interest in this investigation will be: eye, nose and throat irritation, lower respiratory tract symptoms (cough, wheeze, shortness of breath and chest tightness), odour detection and odour annoyance, and general health perception.

6.3 Study approval

Approval has been sought and given by the University of Sydney's Human Research Ethics Committee (Ref No. 04-2006/3/8919-Adults and Ref No. 04/2006/3/9027-Children).

6.4 Sample Size

6.4.1 Questionnaire Survey

The 12 month period prevalence of wheeze in Australian adults is 28% (Abramson, 1996). If 11% of the population who did not have wheeze before the tunnel opened develop wheeze after the tunnel opens and 5% who did have wheeze before the tunnel do not have it after the tunnel opens, then this net 6% increase in the prevalence of wheeze can be detected in a population of 370 subjects (80% power, alpha = 0.05). With this number of subjects, there would also be 80% power to detect a difference between 4% in whom wheeze resolved and 9.5% in whom wheeze developed (a net 5.5% increase in the prevalence of wheeze). We estimate that approximately 75% of subjects who complete the baseline survey and consent to be re-contacted one year later will actually complete an interview at the follow-up survey. Hence, 500 subjects who complete the baseline interview and consent to be re-contacted in 2007 will need to be recruited in each study area, making a total of 2000 adult subjects.

We will recruit 500 households from each of the four exposure zones. From each household we will recruit all eligible residents between the ages of 2-75 years who spend at least one hour at home between 7-9.30am or 4.30-7pm. The primary adult will be asked to complete questionnaires on behalf of their children. We hope to recruit at least 500 adults and 500 children from each study area.

6.4.2 Diary Study

We estimate that it will be feasible to recruit 90 eligible subjects in each of the four study areas, allowing for a retention rate of 60%, leaving 50 participants. Each subject will provide data for up to 9 weeks (63 days) before and after the opening of the tunnel. Sample size calculations were performed assuming that the participants are divided into four exposure groups before and after the tunnel opens. The outcome of interest is the difference in mean FEV1 between each of the exposure groups compared to the control exposure group. It is assumed that each participant will have 63 (repeated) measures of FEV1 during each 9 week period before and after the tunnel opens. Assumptions were: (a) within-subject standard deviation is FEV1 (repeatability) = 200 ml; (b) autocorrelation in FEV1 measures is 0.6; (c) alpha=0.05 and power=80%. Sample sizes were estimated for detecting a 90 ml difference in mean FEV1 between each of the exposure groups compared to the control group. Calculations were performed in NCSS PASS software using the "Advanced repeated measures ANOVA power analysis procedure".

6.5 Study design

6.5.1 Questionnaire Survey

A sample of residents in these areas will be surveyed by questionnaire during 2006, before the tunnel opens and then again 12 months later, after the tunnel opens. A sub-group of subjects in each of these areas who agree to participate in the Diary study will be recruited for that study. They will be asked to record symptoms and peak expiratory flow rates daily, for a three month period, at the same time of year in 2006 and 2007 (Section 6.5.2).

The effect of living in the area at risk of increased exposure to vehicular-traffic pollution will be assessed by comparing the change in health outcomes in that area with the change in health outcomes over the same time interval in the control area. Similarly, the effect of living in the area expected to experience a reduction in traffic-related air pollution will be assessed by comparing the

change in health outcomes in that area with the change in health outcomes over the same time interval in the control area.

All households within each of the four exposure zones will be eligible. People residing in the house aged between 2-75 years will be eligible for the study. Only residents who are not expected to be staying at the same address in one year's time and who are not regularly at home for at least one hour during the morning or evening peak hours will be excluded.
Recruitment of adults will occur through a household doorknock survey undertaken by a market research company, McNair Ingenuity Research. At the time of the home visit an introductory letter about the study will be given to the householder. The nature of the study will be discussed and consent to proceed will be sought. If consent is given, the adult with whom initial contact is made at the door will be interviewed about their health and their child's health using a standardised questionnaire. Self-completion questionnaires will be left for adults not present at that time. Up to three follow-up phone calls will be made for return of the self-completion questionnaires.

The interview will record information on eye, nose and throat irritation, lower respiratory tract symptoms (cough, wheeze, shortness of breath and chest tightness), odour detection and odour annoyance, and perception of general health over the preceding three month period. Information on potential effect modifiers and time-variable confounders will also be obtained. These include sex, age, exposure to cigarette smoke, type of fuel used for cooking, use of air conditioning, use of unflued gas heaters, internal garaging at home, and "environmental worry". At the end of the interview, subjects will be asked to consent to be contacted again at the same time of the year in 2007 for a follow-up interview. Parents will also be asked for their consent for their child to participate in the Diary Study.

If initial contact cannot be made, up to 3 household calls will be made before deciding that a dwelling is unoccupied. A further call will be made to leave a household questionnaire package with pre-paid postage at the address. If questionnaires are still not returned, the address will be matched to the reverse-electronic White Pages telephone directory and we will attempt to recruit to the Questionnaire Survey through a telephone interview.

The follow-up interview, to be conducted within two weeks of the same date in 2007, will have the same content as the baseline interview (except that it will not be necessary to ask again about sex and age).

6.5.2 Diary Study

Those who consent to participation in the diary will undergo baseline health outcome measurements during the second half of 2006. It is intended that children and adults will be recruited into the Diary study using equal numbers in two strata: symptomatic and non-symptomatic. Symptomatic subjects will be defined as those who have had cough or wheeze within the previous 3 months. Due to the time constraints of the study, children will be recruited sequentially into the Diary study as the WIMR receives notification of consents from McNair Ingenuity. Adults who complete the questionnaire will be stratified into symptomatic and non-symptomatic, and then randomly selected for inclusion into the Diary study in equal numbers.

Participants will be phoned to arrange a home visit by WIMR researchers. An information statement together with a consent form will be given to participants and parents of children at the time of the home visit. At this visit the subjects will be provided with multiple copies of the weekly symptom diary, a peak flow meter and return pre-paid envelopes. The use of the peak flow meter and diary card will be demonstrated and explained.

The diaries will record symptoms, medication use and peak expiratory flow rate twice daily. The following symptoms and medications will be recorded: (i) eye, nose or throat irritation (ii) daytime wheeze, shortness of breath or chest tightness, (iii) daytime cough, (iv) sleep disturbance due to respiratory symptoms; and (v) use of bronchodilator medication.

Peak expiratory flow rate is an indirect measure of airway calibre that is commonly used in monitoring airway function, typically in patients with asthma. It is measured using a handheld device. Subjects are requested make the measurement soon after waking and in the evening, before taking their respiratory medications (if any). They are asked to take a deep breath in then blow air out forcefully through the device. The manoeuvre is repeated three times and the highest of the three readings is recorded in the diary.

Additional measurements will be undertaken at the home visits. In 2006 spirometric function will be recorded along with exhaled nitric oxide concentration. These measurements will be repeated in the 2007 home visits. In addition, skin prick tests to test for atopy, and buccal cell swabs to collect cells for DNA analysis will be performed. Analysis of buccal cell swabs will be subject to additional funding being available, and DNA will only be tested for genetic polymorphisms which are associated with lung function and the adverse effects of air pollution.

A report of the results of the breathing and allergy tests will be provided to each child at the time of the home visit.

6.6 Assessment Instruments

6.6.1 Questionnaires

Three closely related questionnaires will be used: one questionnaire administered to primary adult respondent, another questionnaire for other adult respondents in the household and a third questionnaire for children. Each household will be identified by a unique identifier and all questionnaires arising from the same household will be linked through this identifier. Information relating to household characteristics, such as garaging, methods of cooking and heating etc, will only be asked in the primary adult survey. The adults and children's survey will also differ in that the adult's survey will include questions on odour, irritation, and environmental concern, whereas the children's surveys will not.

6.6.2 Symptom Diaries

Participants (or their parent) will be asked to record symptoms, medication use and peak flow measurements twice daily, soon after awakening in the morning and before going to sleep in the evening. Three peak flow measurements will be taken at each time point and the highest of the three readings will be used in further analyses. Upper and lower respiratory tract symptoms and use of bronchodilator medications will also be recorded.

6.6.3 Tests

Height and Weight
Height and weight will be measured during each assessment, using a stadiometer (height-cm) and scales (weight-kg).

Spirometry
Spirometric lung function will be measured on each occasion of testing using spirometers linked to a laptop computer for on-line data acquisition. Subjects are requested to take a deep breath in and then exhale fully and forcibly into a mouth piece that is connected by tubing to the spirometer. On

each occasion after the initial assessment, this will be performed before and 10 minutes after the administration of salbutamol 200 μg (bronchodilator) by large volume spacer.

Testing will be performed in accordance with the standards of the American Thoracic Society except that a six second exhalation time will not be required. The procedure is to be done in the standing position with a nose clip on. If the participant does not tolerate a nose-clip then the technician will "pinch" the participant's nose. If he/she does not tolerate this, then the procedure will be done without any nose clip. Care is taken to ensure that the participant stands upright (ie does not lean forward) while performing the manoeuvre and that he/she has an adequate seal around the mouthpiece.

The aim is to achieve two acceptable spirometric manoeuvres with the best two FEV_1 (and FVC) values within 100ml or 5% of each other (whichever is the greater). Care is taken to ensure that the participant stands upright (ie does not lean forward) while performing the manoeuvre and that he/she has an adequate seal around the mouthpiece.

Acceptable manoeuvres are those with a rapid start (steep first part of the flow volume curve) and adequate duration. Adequate duration is defined as no rapid cessation of flow from a point at which the flow rate is more than 10% of the maximal flow. The first of these criteria is essential for both FEV_1 and FVC recordings. However, if the participant cannot achieve the second of these criteria (and the curve is adequate for at least one second) then it should be considered acceptable for the purpose of measuring FEV_1 but not acceptable for the purpose of measuring FVC.

Procedure:
1) Explain and demonstrate the procedure
2) Perform the procedure and correct any errors in technique
3) Repeat the procedure until at least three acceptable flow volume loops have been recorded
4) If the best two acceptable values of FEV_1 or the best two values of FVC are more than 5% and more than 200ml different then repeat the procedure up to two more times (until the best two are within this margin).

The following data are recorded for each spirometry session (ie before bronchodilator and after bronchodilator)
a) Time since last shorting-acting bronchodilator
b) Time since last long-acting bronchodilator
c) Number of acceptable attempts
d) Best two values for FEV_1 from the acceptable flow-volume loops
e) Best two values for FVC from the acceptable flow volume loops
f) Best two values for PEFR from the acceptable flow volume loops

Note that the FEV_1, FVC and PEFR values chosen do not have to come from the same flow volume loops.

For administration of bronchodilator, one puff of Ventolin via spacer is given and the participant is asked to take 5 breaths, then one minute later a second puff of Ventolin is given and the participant is asked to take another 5 breaths. A second spirometric lung function test will be performed to determine and change in lung function post-bronchodilator.

Skin Prick Tests
Skin prick tests will be performed to detect the presence of atopy at the second round of testing in 2007 only.

A stamp is placed in the volar of the forearm to mark the location of the test droplets. A tiny droplet of each allergen is positioned on to the skin in the appropriate squares marked out by the stamp. There are also two extra droplets that are used for negative control (glycerine) and positive control (histamine 6mg/ml). Then a lancet is passed through the drop just catching the skin at anywhere from a 20° to an 80° angle and then it is lifted, creating a small break in the epidermis. After 10 minutes of completion of the skin pricks a measuring grid is used to record the size of each of the wheals (lumps) that have occurred. The largest diameter and its perpendicular are recorded. The wheal size is recorded as the mean of these two measurements, rounded up to the nearest 1 mm. Wheals larger than 3mm in diameter and larger than the negative control are considered to be positive. The allergens tested are house dust mites (D. pteronyssinus, D. farinae), mould (Alternaria), cat pelt, cockroach, ryegrass, and grass mix (Hollister-Stier). Subjects with any positive skin prick test to an allergen are classified as atopic.

Exhaled Nitric Oxide

Exhaled nitric oxide (eNO) is measured as a marker of airway inflammation. Exhaled nitric oxide concentrations are elevated in people with asthma and also in people with atopy.

The method we will use is an off-line technique where the exhaled breath is collected into a 3L chemically inert bag. The subject first breathes through a NO scrubber five times to remove NO from the ambient air and immediately blows out through a narrow mouth piece into a rotameter. Blowing against a small resistance ensures closure of the soft palate during expiration and excludes air from the nose, which has high levels of eNO. The rotameter is connected to the bag and the air is collected. The bag is then taken for later analysis on the same day. Nitric oxide concentration in collected specimen is measured using a chemiluminescence analyser (ThermoEnvironmental 42C).

Buccal Cell Swabs

Buccal cell samples will be collected and DNA from them will be stored for subsequent screening for genetic polymorphisms that may identify sub-groups of the population at increased risk of adverse effects of air pollution. A sterile swab (Whatman Sterile Omni-Swabs) will be used for each participant. Single use of a sterile swab should ensure negligible infectious risk. Subsequent testing of the buccal cell samples will rely on additional funding. Future analysis will be limited to genetic polymorphisms relevant to lung health and the adverse effects of air pollution.

6.7 Data analysis

Changes in symptom prevalence, lung function and airway inflammation (eNO) between 2006 (before the tunnel opens) and 2007 (after the tunnel opens) will be regarded as an indicator of long-term health effects attributable to traffic related air pollution. Data from both the questionnaire survey and the diary study will be used for this analysis. We will also use symptom diaries to assess the association between day-to-day variation in air quality and health outcomes ie short term changes.

For all participants in the study population, the mean change in clinical measures between 2006 and 2007 (before and after opening of the LCT) will be quantified.

The analysis will take account of the matched pairs or cohort design of the study. Generalised estimating equations will be used with each subject as the grouping variable. For dichotomous variables (symptoms) a logistic link will be fitted and for continuous variables (peak flow, spirometry and exhaled nitric oxide) an identity (linear) link will be fitted. For the symptom diary data, first order autoregressive within-subject correlation will be assumed for the daily observations. Study area and time (before and after the tunnel opening) and the study area by time

interaction will be the fixed effects. This interaction term will be estimated and tested to address the study question, that is, the difference between the areas affected by changes in traffic-related pollution and the control area in the change in health outcomes. Contrasts between each of the areas affected by the tunnel and control area will be estimated and tested.

A separate analysis will be undertaken using individually-assessed NO_2 exposure estimates, instead of study area, as the fixed, independent variable in the model described above. Individual NO_2 exposures will be estimated using exposure metrics described above (Section 4).

Additional analyses of the diary data will test for the presence of differences between areas in the incidence or remission of any symptoms (for each class of symptoms) and in the spread (variance) and minimum values of the peak flow data. These additional analyses will detect transient effects of the tunnel-related changes in pollution.

Finally, a further analysis of diary card data, using a similar GEE model, will include daily 1 hour maximum NO_2 and 24 hour average PM_{10}, obtained from the nearest fixed site monitor, as the fixed effect, instead of time and study area in the previously described model. This will be fitted with various time lags and will be used to assess the relation between daily levels of these pollutants and daily symptoms. These data will also be examined graphically to look for the effects of transient peaks in exposure.

7 PICNIC STUDY

7.1 Exposure around the stacks

The immediate area around the western ventilation stack is predicted to experience a 20% improvement for NO_2 and a 2% improvement for PM_{10} (annual averages), whereas the eastern stack is predicted to experience no change for NO_2 and an approximate 1% deterioration for PM_{10}. The predicted improvement in air quality around the western stack is attributable to the decrease in traffic flow in surrounding streets, particularly Epping Road. In contrast the eastern stack is near the feeder roads to the tunnel and the Pacific Hwy and will be exposed to increased emissions from these roads.

Further modelling work was conducted by the project proponents of the ventilation stack emissions to estimate whether ambient air quality would comply with air quality standards given a worst case scenario for meteorological, and tunnel conditions and high vehicular counts. This modelling found that:

- Only a very small area around the ventilation stacks is predicted to experience an increase in NO_2 and PM_{10}. This area will have only a very small residential population residing within it as most of the area around the stacks is industrially zoned.
- The eastern stack is also located close to the feeder roads to the tunnel, and so attribution of an effect solely due to the stacks may be very difficult.

The short term peaks for these pollutants under worst case scenarios are expected to comply with existing air quality standards. This is a similar situation to that of the M5East tunnel and stacks prior to construction. However, after the tunnel opened some residents living near the M5 East ventilation stack complained about symptoms associated with short term exposures, such as eye (soreness, scratchiness, dryness, grittiness, burning and watering), throat (soreness, dryness), and nose (itchiness, sneezing, dryness, runny, congestion) irritations. For this reason, the LCT study will also incorporate a population living close to the ventilation stacks in an attempt to capture

health outcomes associated with short term exposures to those emission sources (Questionnaire and Diary study). Here we describe an additional study designed to assess the impact of emissions from the ventilation stack.

7.2 Aims

The aim of this investigation is to test the hypothesis that there are detectable effects of exposure to emissions from the LCT ventilation stack on:

(a) Perception of, and annoyance due to, odour;
(b) Irritant symptoms in the eyes, nose, throat and chest;
(c) Lower respiratory tract inflammation; and
(d) Spirometric lung function.

To achieve this aim we will implement an experimental design that is loosely based on a "picnic" study that has been undertaken in London with funding from the Health Effects Institute.

7.3 Study Design

Testing the study hypothesis requires measurement of the study outcomes during exposure to ventilation stack emissions and in the absence of ventilation stack emissions. The study design needs to take account of a number of potential sources of measurement error, both random and non-random (bias), as well as potential confounding factors. These extraneous sources of variation include:

i. Between- and within-subject variation in constitutional susceptibility to health effects;
ii. Between- and within-subject variation in expectations that may influence measured health effects (due to obvious proximity to the ventilation stack and the obvious opening of the LCT); and
iii. Time-variable and location-variable confounding environmental factors including meteorology, which may affect exposure to stack emissions and may also directly affect health outcomes, and ambient biological and non-biological contaminants from distant sources (ie not associated with the ventilation stack).

In order to account for these factors, we have designed a randomised, parallel-group controlled trial with an additional three-way cross-over (Table 7.1).

Subjects will undergo a series of environmental exposures before and after the opening of the tunnel. Each exposure will consist of two periods of two hours of easy walking (2 x 30 min each morning) within the defined exposure areas, commencing at 7am on two consecutive days.

A number of ventilation stack exposure sites and a control site (not expected to experience a change in air quality between 2006 and 2007) will be defined. Within the ventilation stack exposure site two sub-sites will be defined by considering the meteorological conditions on the measurement day.

Forty subjects will be recruited and randomly assigned to one of three groups (A, B and C). Each of the three groups will undergo two ventilation stack exposures and the one control site exposure during 2006 (prior to tunnel opening) and again one year later (after the tunnel opens).

Table 7.1 Assignment of exposure periods

Period	Week	LCT ventilation stack		Control
		Site 1	Site 2	
Before (2006)	1	A	C	B
	2	B	A	C
	3	C	B	A
After (2007)	1	A	C	B
	2	B	A	C
	3	C	B	A

7.4 Study Population and Sample size

7.4.1 Subject inclusion criteria (target population)

The study population will be volunteer adults, aged 18 years or over. Advertising for the study will favour those people who state that they regard themselves as sensitive to the effects of strong smells and odours (cigarette smoke, perfumes and household sprays). Subjects will be ineligible if they:

i. have a loss of sensation of smell.
ii. are pregnant
iii. have been smokers (more than one per day) within the preceding 12 months
iv. have co-morbidity likely to limit their ability to walk for two hours
v. are unlikely to be available for the second phase of the study (in 2007).

Subjects will be recruited by advertisement. Each subject will be reimbursed for each morning testing session as recompense for time and inconvenience.

7.4.2 Sample Size

A recent study in London was able to detect within-subject differences in lung function in 26 subjects (with asthma) exposed to a high pollution area and a low pollution area (1). On this basis, our study design, which incorporates more repeated measurements in each individual, should be adequately powered if 75% of the 40 recruited subjects complete the study.

7.4.3 Recruitment

Volunteers for the study will be recruited primarily through advertising at the University of Sydney through direct posters, email groups, and through various faculties. Posters will also be advertised at the University of NSW and Macquarie University. Advertising through the NSW Health email network will also be targeted. Subjects will also be recruited from the Woolcock Institute of Medical Research's Volunteer Database.

7.5 Assessment instruments

7.5.1 Subject baseline assessment

Subjects who use long-acting bronchodilators will be asked to withhold these for 12 hours prior to testing and those using short-acting bronchodilators will be asked to withhold them for 6 hours.

Subjects will complete a routine assessment questionnaire to record the presence of pre-existing eye, nose, throat or respiratory symptoms, treatment for these symptoms, and prior history of smoking. They will also complete the 11 item Chemical Sensitivity Scale – Sensory Hyperreactivity

The presence of atopy will be assessed using skin prick tests to common inhaled allergens. We will test the following allergens: house dust mites (D. pteronyssinus, D. farinae), moulds (Alternaria), cat pelt, cockroach, ryegrass, and grass mix (Hollister-Steir). The presence of any allergen weals ≥ 3 mm and > the negative control is indicative of the presence of atopy. Spirometry and exhaled nitric oxide will also be measured at the baseline assessment.

7.5.2 Outcome assessment

The focus of this study is on perception of symptoms and objective measures of airway inflammation and airway function. All assessments will be made at the following three time points after the commencement of exposure for each participant: 05 mins, 40 mins, 80 mins.

Irritant symptoms of chest, nose, throat and eyes

These will be measured using a visual analogue scale. Respondents will be asked to mark a point on a line indicating how they feel at that point in time.

Odour symptoms

Subjects will be asked if they can detect an odour or pungent smell. If they can, they will be asked to quantify how strongly they can smell it and how annoying it is, using a visual analogue scale (VAS).

Exhaled nitric oxide

Exhaled nitric oxide (eNO) is measured as a marker of airway inflammation. The method is as outlined in Section 6.6.3.

Spirometric function

The method is as outlined in Section 6.6.3.

7.5.3 Exposure assessment

The primary, intention-to-treat, analysis will assign exposure based on the experimental design, as described above. However, during each two hour testing period, we will collect 3 L air samples from the mid-point of the exposure zone at 15 minute intervals. These will be used to measure oxides of nitrogen (NOx) using a ThermoEnvironmental 42C NOx chemiluminescence analyser at the Woolcock Institute of Medical Research. We will also measure exposure to fine particles and air toxics (BTEX: benzene, toluene, ethylbenzene, xylene) during the exposure periods. These data will be used to examine the extent to which our expectations about differences and changes in air quality are fulfilled.

7.6 Procedure

The nature of the study will be explained to subjects and written informed consent will be obtained. Baseline assessment, as described above, will be undertaken at the time of recruitment. After this, subjects will be randomly assigned to groups.

Testing will be performed on Tuesday and Wednesday of each week, subject to weather conditions. On each testing day, subjects will meet at the Woolcock Institute of Medical Research at 6:30am, 30 minutes prior to scheduled start. Alternatively, participants can choose to travel directly to the sites. Regardless of the mode of travel to the sites, they will be asked to wear a N95 respiratory mask, designed to filter out fine particles from the time they leave home to the time they arrive at the testing sites. During this period, those assigned to exposure at the ventilation stack sites will be driven to the site in a mini-van. Those assigned to the control exposure will wait at the Woolcock prior to taking up their positions adjacent to Parramatta Road at 7am.

At the testing site, subjects will exercise within the defined exposure area and will undertake assessments as described above. At the conclusion of the testing period they are free to return home directly or be transferred back to the Woolcock.

If weather conditions are not suitable (strong winds and/or rain), the test day will be deferred to another day in the same week or to the same day in the following week.

7.7 Data analysis

A regression model will be constructed to test the effect on study outcomes of exposure to the plume-landing site from the ventilation stack with the tunnel operating compared with exposure to the same site when the tunnel was not operating. All between- and within-subject experimental sources of variance will be modelled.

VAS scores, eNO and spirometric function will be treated as linear variables. Experience suggests that eNO and spirometric function residuals will be normally distributed and that VAS residuals will be skewed. Hence, the latter will be transformed if required.

8 DATA PROCESSING FOR ALL STUDY COMPONENTS

8.1 Database management

The database will be designed by the WIMR.

To assure the quality of the database, the following issues are considered:

- Data type, e.g. numeric, alphabetic, binary, date, etc.
- Data size or maximum allowable length
- Permitted range of values
- Coding
- Validation of permitted values
- Primary key/s to the database
- Missing data
- Database documentation

McNair Ingenuity will provide checked Questionnaire data to WIMR in the form of Excel spreadsheets. Health outcome data arising from the Diary study will be double-entered into the two replicas of the database by two independent operators and then cross-checked by the database manager. The consistency checks, checks for missing data and validation of data range will be performed by the database manager. All errors that are detected at this stage, together with the details of their correction, will be recorded in the data management report.

The final version of the database will be stored in secured location, with User-Level security system, to protect the data from an unauthorized access. Regular back-ups will be provided by the WIMR IT department.

9 PARTICIPANT SAFETY/CONFIDENTIALITY

Consent will be sought from adults, and children and their parents for each of the two stages of recruitment: the Questionnaire Survey, and the Diary Study. Participation will be voluntary and children or adults will be able to withdraw from the study at any stage.

All results will be de-identified. The raw data, including that relating to the identity of subjects, will be accessible only to the investigators involved in the study. Participant identification and the raw data will be filed separately. On the computer database, the data will be stored in password protected files. The data will be reported in such that a way that no individual subjects can be identified. The raw data sheets, containing the clinical data, will be stored in a secure data archive in The Woolcock Institute of Medical Research. The data will be transferred to a computer database, using the subject identification code to identify individual subjects, for analysis of the complete data set.

After analysis and publication, the data will be stored in the data archive in The Woolcock Institute of Medical Research for at least seven years, where it will be accessible only to the investigators. When the investigators agree that the data are no longer required the raw data sheets will be shredded and the computer files erased.

Approval has been sought and provided from the University of Sydney's Human Research Ethics Committee.

10 QUALITY CONTROL

McNair Ingenuity Research routinely conducts double entry to 20% of its questionnaire data. Telephone calls will be made to the household where data is missing or is inconsistent.

The Woolcock Institute of Medical Research has extensive experience in performing the respiratory tests which are to be performed in the study. There are some procedures that are taken into account when performing fieldwork to assure that quality data is collected and to minimise possibilities for error in testing, collection, interpretation and analysis.

Experienced epidemiological team members will comprise part of the team that will perform the tests and also will train and supervise more junior or recent staff members. All staff will be trained in all protocols in a special training session prior to starting field work. During the training session, tests will be administered to staff members from staff members and an explanation of quality and safety issues will be undertaken to ensure thorough understanding.

The spirometers will be calibrated with a 3L calibration syringe at the start of each day and after any component of the spirometer is changed.

The questionnaires will be checked for completeness and when answers are missing, these will be obtained by calling participants by telephone. We will ask that symptom diaries be posted to the WIMR on a weekly basis so that they can be checked at this frequency. Where it appears that the diaries are not being completed appropriately or that peak flow measurements are not being undertaken, a follow-up phone call to the family will occur. In addition, a follow-up phone call to each family will occur regardless, to help maximise completeness of the diaries and PFM.

The WIMR will conduct double entry of all health outcome data into the database.

11 RISKS TO THE PROJECT

A number of potential risks are associated with conducting this study, and are outlined below:

Delay in opening of the LCT tunnel. This is unlikely given past experience with privately funded infrastructure of this kind. Recent statements by the construction company, Thiess/John Holland, indicate that it is on schedule to open the tunnel in December 2006.

Delay in use of the LCT. Although there is a potential for a delay in uptake of use of the tunnel, as has been experienced with Sydney's Cross City Tunnel, we do not expect that this will occur to any great extent for the LCT. The LCT will service an existing heavy commuter flow.

Delay in change in traffic conditions along Epping Rd. As a result of the Lane Cove Tunnel Inquiry report, the government has announced that narrowing of Epping Rd will be postponed until tunnel and surface road usage patterns are established post tunnel opening. These may defer the full impact of the tunnel in producing the expected changes in traffic-related air pollution.

12 REPORTING OF STUDY RESULTS

The results will be presented at relevant scientific meetings and published in peer-reviewed scientific or medical journals. A report will also be written for the NSW Health Department.