

The Latrobe Early Life Follow-up Study: the child health and development stream of the
Hazelwood Health Study

The Latrobe ELF Study Information Sheet

Thank you for taking the time to read this information sheet which is yours to keep.

You are invited to take part in the Latrobe ELF Study – the child health and development stream of the Hazelwood Mine Fire Health Study. This information sheet has been written to help you decide if you would like to participate in this study. Please read this sheet carefully and feel free to ask questions before signing the consent form.

What is the study about?

During February and March 2014 a coal fire burned in the Hazelwood mine causing a period of smoky conditions in the Latrobe Valley. The Hazelwood Mine Fire Health Study is a research program that will investigate whether the smoke from the fire has affected the health of local residents. There are three main studies in the overall research program:

1. *The Latrobe Early Life Follow-up (ELF) Study*
2. *Hazelwood Schools Study*
3. *Hazelwood Adult Survey & Health Record Linkage Study*

You are being invited to participate in the Latrobe Early Life Follow-up (ELF) Study.

Please note: You may also be invited to participate in the other parts of this research program.

The aim of the Latrobe ELF Study is to find out whether the smoke from this fire affected the health of babies and children in the years following the fire. No studies like this have been done before and it is not known if there will be any longer term health issues identified. We want to find out if the smoke exposure affected things like the birth weight of babies whose mothers were pregnant at the time of the fire, the number of common infections like colds and sore ears in the first few years of life, or the early development of the lungs and blood vessels. Finding out about this will help the management of future severe smoke episodes from bushfires or other fires.

Who can participate in the study?

Children who were born between 1 March 2012 and 31 December 2014, and whose parents were residents of the towns of Morwell, Moe, Churchill, Traralgon, Newborough, Yallourn North and surrounding towns during the period of the Hazelwood Mine Fire are eligible to join this study. In addition, children who were born between 1 January 2015 and 31 December 2015 and whose parents were residents of the towns listed above during February and March 2015 are eligible to join.

What does the study involve?

The study has five main parts:

- *Completing a survey*

This survey asks for information about your child during the period of the fire. It collects information about the houses the study child has lived in up to the age of 2, as well as the houses the study child's mother lived in the year before the child was born. This includes the type of heating and cooking used in the home, if householders smoke indoors or outdoors, and if your child or their close relatives have had any health problems, especially those affecting the heart or lungs. It asks about

This study is being conducted in cooperation with:

family circumstances such as employment, education, country of birth and languages spoken at home. The questionnaire may be completed in a number of ways including over the phone by Hunter Research Foundation, an agency that the researchers have asked to conduct the questionnaire, over the internet, on paper or face to face with a study team member who will visit your home.

- *Collecting soil and dust samples from your home*

If you are willing to provide us with small samples of dust from your vacuum cleaner and soil from your yard which we will test for chemical markers of coal smoke, we will provide plastic bags, collection spoons and instructions on collecting soil and dust. These can be posted back to us in a reply prepaid envelope that we will provide.

- *A monthly child health diary*

This is a simple tick box record of some common lung, skin or ear problems, if you saw a doctor about these, and what the doctor told you were the likely causes of the problem. We will contact you via SMS once a month. Responding will usually just take a few minutes.

- *Permission for data linkage*

Data linkage is a way of connecting common health information held by different groups or services. It can be done in a way that protects a person's privacy. For example, we may ask for your consent to allow the researchers to access your child's Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined on the back of the consent form. Medicare collects information on doctors' visits and procedures, while the PBS collects information on the prescription medications dispensed at pharmacies. You may also be asked to consent to have your child's name searched and data extracted from other health and human service databases, such as birth, hospital, emergency, and education databases. These services routinely collect this information, and providing consent means that the study investigators can access and link this data. The consent form would be sent securely to the Commonwealth Department of Human Services who hold this information confidentially.

- *Participating in simple lung, heart and blood vessel checks*

Later in the course of the study (starting in 2017), we will invite a subgroup of 500 children to have some simple tests to measure their lung and blood vessel function at the Latrobe Regional Hospital. These tests include breathing into a device, checking height, checking blood pressure (with an inflatable cuff that causes a squeezing sensation), and having an ultrasound of the blood vessels in the abdomen and neck. Ultrasound is a safe and painless test (similar to the test that is used in pregnancy to check on the baby's development). The measurements will be taken by specially trained staff and will occur in the later years of the study. Parents will be encouraged to be present for the testing. If your child is involved in this part of the study, further explanation about what is involved will be provided closer to the time. There will be no cost to you for these tests.

If you choose to participate in the Latrobe ELF Study, data collected for the study may be shared with other studies involved in the Hazelwood Mine Fire Health Study research program, to better understand the impact of the mine fire across the community.

Are there any risks or inconveniences associated with this study?

The study does not involve any risks to yourself or your child. All of the information we are collecting will come directly from asking you, accessing health databases or performing simple measurements on your child.

The main inconvenience associated with the study will be the time required for your participation. The first questionnaire will take between 30-45 minutes to complete.

The time required for the monthly reports of any lung, skin or ear infections will be much shorter, less than one minute if your child has been well in the previous month, and 5-10 minutes if your child did have an infection or visit to the doctor. Collection of the soil and dust samples will only be required once and is anticipated to take 30-45 minutes. Participation in the lung and blood vessel measurements in the later years of the study will require approximately 1-2 hours of you and your child's time on 3

occasions. These are currently planned for years 3, 6 and 9 of the study.

Whilst you will not receive any direct benefits from participation in the study, the study will address community concerns regarding the health impacts of the smoke event and will assist communities and governments to respond to similar events in the future. The first 500 families to enrol and complete the survey will receive a \$25 grocery gift voucher to thank you for taking the time to participate.

We are not in a position to provide medical care or advice. If you have any questions or concerns about your or your child's health we recommend you make an appointment with your usual doctor to discuss these. If your child participates in the lung, heart and blood vessel checks in the later years of the study, the researchers will notify you in the event of an abnormal result and provide details along with a referral letter to your family doctor.

What if I do not wish to participate?

Your participation is voluntary. If you do not wish to participate in the Latrobe ELF Study, then let us know by:

- Advising Hunter Research Foundation when they call you, or
- Completing and returning the enclosed consent form in the reply paid envelope supplied, indicating that you do not wish to participate, or
- Contacting the Latrobe ELF Study team at the University of Tasmania on 1800 322 102, or,
- Emailing the Latrobe ELF Study team on Latrobe.elf@utas.edu.au with your name and address.

If the study team does not hear from you by XXXXXXX, then we will ask Hunter Research Foundation to call you.

If you let us know that you do not wish to take part in the study, we will make sure that you are not contacted by the Latrobe ELF Study team again. However, you may be invited to participate in other Hazelwood Health studies involving older children or adults. You will also have the option not to take part in these studies.

You and your child are free to withdraw from the Latrobe ELF study at any time.

How will the information you give for the study be managed?

Any identifiable information that is collected about you or your family in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. All paper documents will be kept on premises at the Menzies Institute for Medical Research and Monash University. All records will be kept in locked filing cabinets or in password protected computer files - accessible only to named investigators on the project, or to contracted providers who are administering the surveys. Only authorised project staff will have access to your details and results. Your child will not be able to be identified in any of the documents published about the study. Your child's information will only be used for the purpose described in this information sheet. If we would like to use any of your information for any other purpose, now or in the future, we will contact you again to ask for your permission. You can request that your data be withdrawn from the study at any stage prior to the publication of project reports.

If you choose to participate in the Latrobe ELF Study, data collected for the study may be shared with other studies involved in the Hazelwood Mine Fire Health Study research program, to better understand the impact of the mine fire across the community.

With your consent, we will store your and your child's information so that we will be able to contact you about future related research projects.

If you do not want to be part of a long term follow up we will permanently remove all identifying information from your data after holding it for the required minimum of 7 years from completion of the research in accordance with the National Health and Medical Research Council and the provisions of the *Privacy Act 1988*. Paper copies will be shredded and all electronic copies will be deleted.

Results

Findings from all aspects of the Hazelwood Mine Fire Health Study will be shared with the community through the community advisory group and other community organisations, as well as on the study website. If you would like to be informed of the overall research findings, please contact us - our contact details are below.

Who runs the study?

The study is funded by the Victorian Department of Health and Human Services (DHHS), and is conducted by a group of researchers from universities across Australia. The Chief Investigator of the study is Dr Fay Johnston from the Menzies Institute for Medical Research at the University of Tasmania. While DHHS has funded this research, only the research team will have access to data gathered in the study.

Who can I contact about the study?

You can contact the study support line on **1800 322 102** to ask a question about your participation. Alternatively you can email Latrobe.elf@utas.edu.au, or contact us via our website at <http://hazelwoodhealthstudy.org.au/contact-us/>.

If you would like to contact the researchers about any aspect of this study, please contact Dr Fay Johnston at the above email or telephone number or via the Menzies Institute for Medical Research, 17 Liverpool St. Hobart 7000.

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee, and the Monash Health Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, please contact:

1. The Executive Officer of the Tasmanian HREC on (03) 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote H0014875.

OR

2. Ms. Deborah Dell, Manager, Monash Health Human Research Ethics Committee on (03) 9594 4611. You will need to quote Project 16002L.