Plain Language Statement – Clinic Assessment

Melbourne School of Population and Global Health,
Faculty of Medicine, Dentistry and Health Sciences,
The University of Melbourne

HREA Project Number:	82288
Research Project Title:	*The follow-up of the Tasmanian Longitudinal Health Study (TAHS) from first to seventh decade*
Principal Researcher:	Professor Shyamali Dharmage
Version Number:	3.0

This document contains detailed information about the above study. Its purpose is to explain to you as clearly as possible all procedures involved in this study before you decide whether or not to be involved.

Please read the information carefully. You are welcome to contact a member of the research team to ask any questions about the study at any time (free call 1800 110 711). Once you have understood the study and what we require of you, when you come for your testing appointment we will ask you to sign the consent form located at the end of this document. By signing the consent form you indicate that you have understood the information provided and give your consent to participate in the study.

About the Study

As you may recall, the Tasmanian Longitudinal Health Study (TAHS), is the study that you first joined in 1968 when you were 7 years old. The TAHS has been running for more than 50 years and has provided a valuable resource for medical research on chronic lung diseases.

Research has shown that chronic obstructive pulmonary disorders (COPD) are major public health issues, and they become more common as people age. We are trying to understand the factors that cause the development and change in lung diseases and allergies over time. We wish to collect information on particular environmental factors and measure genetic factors to see if they influence the risk of developing disease and also if they cause remission of disease. The information collected in this study will be a valuable resource for both current and future research into lung disease.

The Research Centres

For this research study there are laboratory testing centres throughout Australia.

Funding and costs

This study is funded by the National Health and Medical Research Council of Australia. There are no costs involved to you being part of this research.

Why am I important to the study?

You are important to the study because you have been part of the TAHS since 1968.

Do I have to take part?

No. Participation is completely voluntary. You can withdraw at any time without prejudice. If you decide to withdraw from the study, we would prefer to retain any data already collected, but if you would prefer for your information to be destroyed, please let us know.

What will I be asked to do?

The aim of this study is to look at the factors that affect respiratory health in adults by collecting information about your health during a once-off laboratory session. This visit is anticipated to take about 1.5 hours of your time. The testing routine includes:

1. **Clinic Survey:** We have sent a survey questionnaire, via email or mail, to all our TAHS original participants to complete at home before attending the clinical assessment. The clinic survey is a separate screening questionnaire to be completed on the day of your assessment, which includes additional questions about your health. If there are questions that make you uncomfortable, you do not have to answer them. You can just skip them and answer the rest. Completing this questionnaire should take no more than 30 minutes.
2. **Breathing Tests:**

Spirometry*:* This is a standard test used to measure how well your lungs are functioning. You will be asked to breathe in and out to measure the amount of airflow. After the first set of measurements, we will then give you doses of an inhaled medication commonly used in asthma known as a bronchodilator to help open up your lungs. After 10 minutes, airflow measurements will be repeated. We will need to take body measurements (height, weight, and size of hips, waist, and neck) in order to interpret breathing test results.

Forced Oscillation Technique (FOT): This is a unique and reliable method of looking at the narrowing of the airways. By combining the information from the spirometry test and an FOT, we can thoroughly look at your airway conditions. With FOT, an instrument will send low pitch to slightly higher pitch sound waves down the airway. The time that takes the sound wave to travel down the airway and back to the instrument will be measured. Sound waves at different pitches will travel at different distances. This will give us an idea of what is happening along the full length of your airway.

FOT is a non-invasive procedure. We ask that you breathe naturally into the machine while sitting in an upright posture. After just a few breaths, the machine would be able to give us readings about the health of your airways.

Expired Nitric Oxide (FeNO): We would like to measure the concentration of a particular gas (nitric oxide) in your breath. The test involves breathing out into a machine 2 or 3 times. It takes about 3-4 minutes for each breath.

3. **Hand Grip Strength**: This will involve using a hand dynamometer to measure your hand grip strength, as an indicator of overall strength.
4. **Home Blood Pressure Measurements**: Heart rate and blood pressure can indicate general heart health, which can affect your lung health and vice versa. To measure these, we ask you to take home blood pressure machine provided by your clinic tester on the day of your appointment. Twice a day for seven consecutive days, we ask you to place an inflatable cuff around your upper arm. When the blood pressure machine is turned on, the cuff will inflate to a pressure higher than your blood pressure and quickly release as it measures both the blood pressure and pulse. The measurement is non-invasive.

   To record the blood pressure readings, you can:
   - Use a diary provided by your clinic tester. The diary will be returned to the University of Melbourne with the blood pressure monitor, in a return paid satchel.
   - Alternatively, if you have access to a computer or any other mobile devices, we will provide a secure link for you to log your blood pressure readings.
5. **Blood test:** This is an optional test that is performed by trained Clinic Staff at your clinic assessment. We will measure factors in your blood, such as proteins that regulate inflammation, to help study the causes of lung diseases. We will also extract genetic material (DNA) from the cells in your blood. The DNA may be used to look for genes that may help us understand why you or family members have or have not developed lung diseases. Planned use of the genetic material includes studies on known and yet to be discovered genes involved in the development of allergy and lung diseases. This is genetic analysis for medical research and is not the same as a clinical genetic test.

What are the possible benefits?

There are no direct benefits to you by participating in this study, apart from the possibility of new information about your lung function. A great deal of new knowledge will be made available to the medical community through research publications. A possible benefit you may experience could be when physicians make use of the knowledge generated by the study when caring their patients.

What are the possible risks?

Participating in the clinic visit will have minimal effects on your health. The side effects of taking a bronchodilator medication (Ventolin) are not common, but it can lead to slightly raised heart rate or tremor in the hands. This should only last for a few minutes.

The blood sample will be taken by a trained researcher. There are no major risks associated with taking blood. It is possible you may feel some discomfort while taking blood, or you may feel dizzy or light headed. We can use a cream to numb the skin before the blood is taken. It is possible there may be some bruising at the injection site.

It is possible we may find that you have low lung function. In some cases, we will advise you to visit your doctor as they will better manage these conditions. We will mail you a copy of the results within 4 weeks of your visit.

The lung function tests will be performed with COVID-safe procedures approved by Thoracic Society of Australia and New Zealand. CT is not considered an increased risk for COVID-19.

Participating in this study will have no effect on your health (medical) insurance or your access to health care. Participating in this study will have no effect on any life, trauma, or disability insurance policies you currently hold. If any new information about risks and/or side effects becomes known during the project, we will inform you of this.

The study may involve unforeseen risks. If you suffer any injury or complication as a result of this research project, contact the study team as soon as possible. The study team will help to arrange appropriate medical treatment for you. If you are eligible for Medicare, you can get medical treatment to treat the injury or complication as a public patient in any Australian public hospital at no cost to you. If any new information about risks and/or side effects becomes known during the project, we will inform you of this.

What will happen to information about me?

The TAHS is an ongoing longitudinal study and all samples will be stored indefinitely at the University of Melbourne for use in current and future studies of allergies and lung diseases. The genetic material will be the property of the University of Melbourne and the custodian will be the head of the Tasmanian Longitudinal Health Study Management Committee. Your blood sample may be used by TAHS study investigators or other researchers who would be required to submit their proposed use of the samples to the TAHS steering committee. This committee is head by Professor Shyamali Dharmage (The University of Melbourne), the Chief Investigator of the TAHS, and includes, Professor John Hopper (The University of Melbourne), Associate Professor Mark Jenkins (The University of Melbourne), Professor Haydn Walters (Menzies Research Institute Tasmania), and Professor Michael Abramson (Monash University). The proposed use would require approval from a recognised institutional ethics committee.

By signing the consent form attached to this Plain Language Statement, you agree to the relevant research staff collecting and using personal information as set out above for the research project.

Any information that we collect for this research will be treated as confidential. Any genetic materials that we collect from you (i.e your blood sample) will be stored in a de-identified form and only be available by other researchers in a de-identified form. This means that when storing your data, we will remove your name and give the information a special code number. Only the research team can match your name to its code number, if it is necessary to do so. We can disclose the information only with your permission, except as required by law. Privacy and confidentiality of your data will be ensured by storing de-identified data within restricted access, password-protected folder on the University of Melbourne's server.

How is my privacy protected?

We will protect your privacy to the full limits of the state and federal government laws. Your samples and data will be stored securely and separately from any personal information that may identify you. We will not pass personal information between family members or to anyone outside the research team, without your written approval.

Will I be contacted again?

We may wish to contact you from time to time to update our records and to ask you to be part of future studies. We will also send a newsletter periodically to let you know how the study is progressing and what we have found. Only group data will be referred to in all newsletters and nothing that could identify you specifically will ever be released without your permission.

Will I hear about the results of this study?

You can learn about the results of this study through our regular newsletters. You can also visit our website on www.tahs.com.au to learn more about the study and to read our published papers and view past and current newsletters. Alternatively, if you want to read a PDF copy of some of the published papers, you can contact the TAHS project Manager, Alice Doherty (email: doherty.a@unimelb.edu.au)

Where can I get further information?

If you would like more information about the study, please contact the TAHS Team on 1800 110 711 or contact the TAHS Project Manager directly (Alice Doherty, email: doherty.a@unimelb.edu.au).

Who can I contact if I have any concerns about the project?

This project has human research ethics approval from Monash Health Human Research Ethics Committee [ethics ID number*: RES-22-0000-046A*]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Human Research Ethics Committee (HREC) Executive Office via phone: (03) 9594 4611 or Email: research@monashhealth.org. All complaints will be treated confidentially. In any correspondence please provide the name of the research team and/or the name or ethics ID number of the research project.

Should you wish to discuss any concerns about the conduct of the research, you can contact the Human Research Ethics Committee for your testing site as listed below:

State	Site	HREC Contact Details
TAS	All sites	The University of Tasmania Human Research Ethics Committee Tel: 03 6226 2763 Email: human.ethics@utas.edu.au
VIC	The University of Melbourne	Office of Research Ethics and Integrity, University of Melbourne 3010. Tel: +61 8344 1376 Email: research-integrity@unimelb.edu.au

	Monash Medical Centre	Monash Health Research Support Services Tel: (03) 9594 4611 Email: research@monashhealth.org
NSW	Prince of Wales Hospital Clinical School	University of New South Wales Human Research Ethics Coordinator Tel: (02) 9385 6222 Email: humanethics@unsw.edu.au
QLD	All sites	Gold Coast Health Human Research Ethics Committee Tel: 07 5687 3879 Email: GCHEthics@health.qld.gov.au
SA	Repatriation General Hospital	Southern Adelaide Local Health Network Human Research Ethics Committee Executive Officer Tel: (08) 8204 6285 Email: Health.SALHNofficeforResearch@sa.gov.au
WA	Sir Charles Gairdner Hospital	SCGG Human Research Ethics Committee Tel: 08 9346 2999 Email: SCGH.HREC@health.wa.gov.au

Who are the Investigators of each study testing centre?

State	Site	Address	Contact
TAS	Hobart	Calvary Lenah Valley Hospital 49 Augusta Rd Lenah Valley, 7008 TAS	Richard Wood-Baker T: 03 6222 7353 / M: 0407 641 077 F: 03 6222 7579 E: richard.woodbaker@utas.edu.au
	Launceston	Calvary Sessional Rooms, St Luke's Hospital 16 Lyttleton St, Launceston TAS 7250	Richard Wood-Baker (as above)
	Burnie	University of Tasmania, Rural Clinical School North West Regional Hospital 21 Brickport Rd, Burnie, TAS 7320	Richard Wood-Baker (as above) Heinrich Weber T: 03 6430 4550 W: heinrich.weber@utas.edu.au

Thank you again for your assistance with the TAHS.

Yours sincerely,

Professor Shyamali Dharmage (Responsible Researcher)

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Declaration by Participant

- I have read the Plain Language Statement or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I consent to the storage and use of blood samples taken from me for use in:

☐ **This specific research project**
☐ **Future research related to this project (extended consent)**

Name: **Signature:** **Date:**

(Participant)

Name: **Signature:** **Date:**

(Witness to consent)