Plain Language Statement – CT Scan

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:	2.2

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).

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 and a CT Scan.

Clinical Assessment: This visit is anticipated to take about 1.5 hours of your time. You will have already received a separate Plain Language Statement for the Clinical Assessment. Please book this appointment first and then a member of the TAHS research team will be in contact with you about the CT Scan.

CT scan of your lungs: In this study we wish to perform a CT scan of your lungs. For the CT scan, you will lie on a table and the table will move through the middle of an x-ray machine that looks like a large donut. You will be asked to lie quietly and take a deep breath in and hold it for the first part of the scan. A second scan will be done after a deep breath. New research suggests that CT scanning may be a better way to identify early COPD than the standard method of spirometry, a form of lung function testing (blowing tests).

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?

The risks associated with undergoing a CT scan include radiation (X-ray) exposure and finding abnormalities in the scan.

Radiation Exposure – performing a CT scan involves the use of X-rays. In the past, high levels of X-rays were needed for a CT scan, but over recent years there has been a progressive decrease in the level needed. The scan on your lung will be performed after a full breath in (inspiratory), and a complete breath out (expiratory) and will expose you to approximately 3 mSv of radiation. This is about the same amount of radiation exposure you receive living at sea level over one year. In comparison, commercial airline travel increases radiation exposure by 0.003 mSv per hour, and airline pilots receive on average 3 mSv additional exposure each year. The main risk from radiation exposure is the increased risk of cancer. The U.S. Food & Drug Administration (FDA) estimates that a CT examination with an effective dose of 10 mSv may be associated with an increase in the possibility of fatal cancer of approximately 1 chance in 2000.

This increase in the possibility of a fatal cancer from radiation can be compared to the natural incidence of fatal cancer in the U.S. population, about 1 chance in 5 (or 400 chances in 2000).

Radiological Abnormalities – even if you have no health problems related to your lungs, there is the possibility that the scan will detect some previously unknown abnormalities. The chance of this happening increases with age and could need further tests to work out if there is a serious health problem. We will notify you of unexpected findings that are clinically important to review and/or manage further, and a letter explaining this will be sent together with the clinical CT report. Please read this letter carefully and if advised, arrange an appointment with your local doctor who can refer on if needed.

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. CT images will be shared in a secure and anonymised way with our TAHS study investigators at Harvard University and the University of Michigan to enable further analysis.

By consenting, 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 Clinical Assessment 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, West Park Campus Building 4-8 Bass Highway, 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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Consent Form – CT Scan

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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.

Chest CT Scan:

☐ **I DO consent to undergo a computed tomography (CT) scan**
☐ **I DO NOT consent to undergo a computed tomography (CT) scan**

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

(Participant)

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

(Witness to consent)