**Participant Information Sheet**

# Chest x-ray versus low dose high resolution computed tomography in screening Queensland workers for occupational dust lung disease

**Introduction**

You are invited to take part in this research project, called ‘Chest x-ray versus low dose high resolution computed tomography in screening Queensland workers for occupational dust lung disease’, which aims to investigate whether the use of low dose high resolution computed tomography in occupational screening provides improved detection of early stage occupational lung disease.

This Participant Information Sheet/Consent Form tells you about the research project. Understanding the project and knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your usual doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section and comply with the study schedule.

**What is the purpose of this research?**

Occupational lung diseases are a group of diseases caused by prolonged inhalation of dust, gases and fumes in the work environment. The diseases associated with dust exposure, and relevant to this project, include pneumoconioses (coal workers’ pneumoconiosis, mixed dust pneumoconiosis and silicosis), dust-related diffuse fibrosis and chronic obstructive pulmonary disease (emphysema and chronic bronchitis).

For over thirty years, it was thought that these occupational lung diseases had been eradicated from Queensland, until 2015 when black lung was re-identified in coal mine workers. This lapse of three decades has resulted in a large gap in knowledge and experience of the medical community in regard to screening, diagnosis, and management of occupational lung diseases.

This study will compare the current imaging method for screening of occupational lung diseases in dust-exposed workers (chest x-ray) with low-dose high resolution computed tomography (LD HRCT) scan. The study results will provide an evidence-base for potential improvements to the current screening process for workers exposed to dust.

The study will focus on workers with at least 10 years history of dust exposure, as evidence suggests the diseases usually take at least 10 years to develop.

The study will be inclusive of workers, both current and former workers, from the coal, hard rock, construction, and quarry industries. This ensures the study has the greatest diagnostic benefit to workers who are most vulnerable to disease.

The body of work already performed in workers exposed to engineered stone products means that the value in assessing these workers further is more limited compared to the larger, less investigated groups above. Engineered stone-exposed stonemasons will therefore not be included in this study.

It is thought that CT scans are better at detecting the early stage of occupational lung diseases than chest radiography in screening programs for workers exposed to dust. No Australian evidence has been collected to demonstrate this – this study will answer the question about whether the low radiation dose CT scan used in this study picks up more early stage diseases such as black lung, emphysema and silicosis.

*In summary*

With rapid developments in screening guidelines for occupational lung disease and limited Australian evidence, we hope to provide proof-of-principle that this CT scan technology provides an improved standard of imaging compared to chest x-rays for the early identification of occupational lung disease in dust-exposed workers.

**What does participation in this research involve?**

You will be participating in a comparative study investigating how chest x-ray compares to low dose CT for early diagnosis of occupational lung disease. This is the first time that a study like this has been performed in Australia.

If your AMA identifies you as suitable to proceed with this trial, and you provide consent, two scans will be arranged. One of these scans will be an ILO CXR scan, which is a standard scan for occupational health screening. The other scan will be a low dose CT (called a high resolution CT or HRCT), which is new technology using very low levels of radiation. This has not previously been tested in screening for occupational lung disease in Australia.

The CT scan will be done in a fully accredited imaging clinic. It is a scan which is frequently performed in patients across Australia for other lung reasons. There is no dye injection, and no special preparation required. The scan is performed within a CT scan machine, and takes less than 15 minutes. You will be asked to breathe in and out for different scan images.

The chest x-ray and the CT scan can be performed on the same day, depending on the clinic you attend, if you decide to participate. If you have not yet decided about the CT scan when you have the chest x-ray, you can choose to participate and have the CT scan any time within the next three months.

Once you have completed these scans there are no further study requirements, and your care will continue as normal under the guidance of your AMA/treating doctors.

You will not be paid for participating in this study. As part of this research project, the CT scan will be provided to you free of charge.

The costs associated with the CT scan will be covered by a research grant obtained from the State of Queensland through the Office of Industrial Relations and by provision of services from I-MED Radiology on an in-kind basis. The chest x-ray will be performed as standard care.

Please note, if your involvement in this trial means you incur any extra costs, such as related to travel or lost income, these are not covered by the research funding, and are your responsibility.

**What are the possible benefits of taking part?**

For you individually, the CT scan may identify disease (related to dust exposure or other diseases) which are not visible on the chest x-ray. Your doctors can use this information to plan treatment before the disease progresses.

However we cannot guarantee you will receive any benefits from this research; even if you have occupational lung disease, we cannot guarantee that the CT scan will show it better than the chest x-ray. Answering that question is the reason we are doing the study.

For the group of people who are exposed to dust in their jobs, and those who were exposed before leaving the industry, the results of this study may lead to better ways of screening for early diseases which can be targeted by treatment before the disease becomes severe. The study results may also give guidance to appropriate measures across the industry to ensure safer working environments.

**What are the possible risks and disadvantages of taking part?**

The risks of participating are minimal. The amount of radiation given to you in a low dose CT chest scan is very small, and will be kept as low as possible by the technical staff in the radiology clinic. Realistically, the amount of radiation in a low dose CT is only marginally higher than in a chest x-ray – an amount which results in no measureable negative health impact.

The amount of time you will spend having the scans will be longer, but if you decide to participate in the study before attending the clinic, you can schedule both on the same visit.

The risk of your personal health information being compromised is also minimal. Any information (such as reports and images) will be secured like all other radiology imaging. There will be a small amount of data from the scan report and occupational history stored on a web based platform, however there will be no way for this information to be linked back to you individually. Only people with a need to access your information will be able to do so as required for clinical care, or for the purposes of conducting the research as described, by authorised persons only, and while meeting all legal, ethical and policy requirements.

Finally, there is a risk of increased medical intervention in workers who are ultimately not diagnosed with disease, with the associated anxiety and time off work for appointments and travel. Ultimately, the predicted enhanced diagnosis of significant disease is felt to outweigh any risks present in this study.

**What if I withdraw from this research project?**

Participation in this research project is voluntary, and you are free to withdraw at any stage. If you decide to withdraw from the project, please notify a member of the research team before you withdraw (contact details below).

Given this study involves medical imaging, if you decide to withdraw after the CT has been done, the CT images and radiologist reports will not be deleted from the radiology clinic database. This is due to legal requirements about the storage of clinical information. However, if you withdraw from the study, any research-specific data can be excluded from the study analysis on your request. If you withdraw from the study, you will be discharged back to your treating AMA who will continue management as standard.

**What happens when the research project ends?**

You will be notified of your individual scan results by your local referrer, as is routine. At the completion of the research project, all data collected will be analysed and a manuscript prepared for publication in the medical literature. A copy of this manuscript will be provided to you if you would like. Data will be completely anonymous, so that your individual data cannot be identified.

**Data privacy**

By signing the consent form you consent to the researchers collecting and using personal information about you for the research project. Minimal, de-identified information, including clinical information will be stored on a web-based data capture platform. Any information obtained in connection with this research project that can identify you will remain confidential. It will be kept in a secure location within I-MED Radiology at The Wesley Hospital for a period of at least 15 years from the date of final publication. Your information will only be used for the purpose of this research project and will not be disclosed without your permission, except as required by law.

**Who is organising the research?**

This research project is being conducted and organised by Dr Catherine Jones (Principal Investigator) from I-MED Radiology at the Wesley Hospital, Brisbane. The research team is also comprised of the following individuals; Dr Katrina Kildey (Research Manager), Dr Sepinoud Firouzmand (Research Manager). This research is being funded by a research grant from the State of Queensland through the Office of Industrial Relations.

**Further information and who to contact**

The person you may need to contact will depend on the nature of your query. Please direct any questions relating to this study to the Principal Investigator or the Study Manager. If you have questions on your diagnosis, please speak to your AMA. For specific questions relating to patients’ rights or ethics, or concerns regarding the conduct of this study, please contact the Uniting Care Health Ethics Committee.

If you have any treatment related side-effects or complaints, please contact the Principal Investigator. If the matter is serious or potentially life-threatening, please call emergency services on 000, or present to the Emergency Centre.

**Principal investigator contact**

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| Name  | Dr Catherine Jones  |
| Position  | Thoracic Radiologist and Principal Investigator  |
| Telephone  | 07 3371 9588 |
| Email  | research@i-med.com.au |

**Research contact**

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| --- | --- |
| Name  | Dr Katrina Kildey |
| Position  | I-MED Research Manager  |
| Telephone  | 07 3377 5979 |
| Email  | Katrina.kildey@i-med.com.au  |

**Human research ethics committee contact**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact Shannon Lytras, UnitingCare Health Human Research Ethics Committee, on (07) 3232 7500 or

Ethics@uchealth.com.au

**Consent Form**

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## Declaration by Participant

I have read the Participant Information Sheet 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 give permission for my doctors, other health professionals, hospitals or laboratories to release information concerning my imaging (including clinically relevant previous and current image data and reports which help interpretation of my scans), employment screening program results (including occupational history) for the purposes of this project. I understand that such information will remain confidential. I understand that minimal, de-identified information, including clinical information will be stored on a web-based data capture platform (which may be based outside Australia) with no identifying information stored on the platform to allow the information to be identified as mine.

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 study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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| --- | --- | --- |
|   Name of Participant (please print)   Signature   |  |   Date  |

## Declaration by Study Doctor

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|   Name of Study Doctor (please print)   Signature  |  |    Date  |