Information Sheet for Participants

Clinical Utilisation of Respiratory Elastance: the *‘CURE’* Study

-Optimising PEEP in mechanically ventilated patients.

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# Participation

You were recently looked after in the Intensive Care Unit (ICU) because at that time your lungs were not working properly, so a ventilator was used to help you breathe. We are currently conducting a research study looking at safer ways to ventilate patients who have sick lungs.

The study is called a Clinical Utilisation of Respiratory Elastance (CURE) randomised control trial (RCT). A RCT involves a random allocation of yourself into one of two groups. You have either A) received standard treatment or B) received standard treatment with the aid to potentially improve your recovery. In either treatment, breathing data was recorded using a bedside computer with doctors choosing the safest mechanical ventilator setting. You will not know which random allocation you have been assigned whether it be A) or B).

It was not possible to ask you to participate in this study because you were too unwell and had been given sedation. However, we discussed this study with your family, and / or close friends, and / or whanau, who believed you would have agreed to participate if you had been able to provide consent at that time. The information below was considered by your family, close friends, or whanau, when they agreed to the participation in the study. We would like you to consider the same information agreeing to continue participation in the study. You do not have to take part in this study, and if you do not wish to take part, your future healthcare will not be affected.

It is important that you read and understand this information sheet. It describes the purpose, procedures, and benefits of the study and your right to withdraw.

## Introduction

Intensive care doctors and nurses use ventilators to support a person’s breathing in intensive care. Pneumonia, trauma, inflammation, or too much fluid in the lung stops it from working properly. When this happens the lung gets “stiff”; this makes breathing difficult. The lungs become stiffer because the injury or infection causes many of the air sacs, (alveoli) to collapse. This is known as Acute Respiratory Distress Syndrome (ARDS).

Some people with stiff lungs will need their breathing helped by a ventilator. However, the ventilator, keeping them alive, may make their lungs worse. High breathing volumes and/or pressures can damage stiff lungs. Unfortunately, the lung can’t be rested and immobilised like a broken bone, so it is very important we ensure the ventilator does not cause more lung injury.

The stiffness of the lung may be reduced by carefully inflating the collapsed regions using a *“recruitment manoeuvre”* (RM). During a RM the lung is gently inflated over a number of breaths by not allowing the lung to completely breathe out. ICU doctors and nurses do this by increasing the Positive End Expiratory Pressure (PEEP) setting on the ventilator.

**Our research aims to find out if people on mechanical ventilation in intensive care are helped by keeping their lung stiffness as low as possible through use of RMs and optimal levels of PEEP.** In this way, we hope to minimise the damage done to the lung by the ventilator.

## Selection

Your relative or friend has been asked to consider your participation in this study because you were ventilated and had a diagnosis of ARDS.

## The Study

You were ventilated using settings chosen by the ICU doctors. Currently, doctors have no standard way of selecting PEEP, so they use their best guess. Too much PEEP over stretches the lung, while too little PEEP causes collapse. Too much, or too little, PEEP makes the lung stiffer. Every person’s lung is different, and his or her lung condition may also change during their stay in ICU. Therefore, choosing the level of PEEP can be quite tricky, and might not always be right.

The lung’s stiffness, or *elastance*, is measured directly at the bedside using a laptop computer. To help doctors decide the best settings, the PEEP will be changed upwards and then downwards. For each of the changes, their responses will be recorded.

You were allocated to either A) a standard ventilation treatment or B) a ventilation treatment using a computerised method, which selects PEEP according to how stiff their lungs are. A randomised trial means every person, who is eligible to take part in this study, has an equal chance of receiving either treatment. This means the results of this research are not influenced by the ICU doctors or nurses.

If you were in group A) you received usual ventilation care by ICU doctors and nurses. A computer recorded the information from the ventilator, but this did not influence your care.

If you were in group B) **a computer recorded the information from the ventilator and recommend the best PEEP setting on the ventilator**. The doctors used the PEEP calculated by the computer setting if they thought it would help your care. Your lung “stiffness” would have changed over time, so we will also checked your lung stiffness at regular intervals and each time you were turned in bed. The PEEP settings were adjusted as necessary.

### Risks

There was a risk that the PEEP setting suggested by the computer model might not have been the best for your lungs. This risk was minimised by asking the doctor if they agree with the PEEP level suggested by the computer. If the ICU doctor was not satisfied with the computer’s suggestion, they chose another PEEP, which they considered more appropriate. The computer could not adjust the PEEP by itself; an ICU staff member made these changes manually.

**Possible Benefits**

You may or may not have experience any benefits from taking part in this study. However, frequent attention was paid to the way you were ventilated, and the settings were adjusted more than usual, which might have allowed you to get faster better.

If our method is found to help ICU patients in Christchurch, this method could be become more widely adopted, and significantly change the experiences of patients receiving ventilation in ICUs all over the world.

### Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you will be eligible to apply for accident compensation (ACC) within its limitations. If you have any questions about ACC, please feel free to ask the researcher for more information before you agree to take part in this trial.

ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2001 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

### Stopping participation in this study

You are free to withdraw from this study, without having to give a reason, and this will not affect your continuing health care.

The ICU doctors might have stopped your participation in this study, at any time and for any reason. If this did happen, it might have been because your condition had changed, or because of technical problems relating to the equipment. In any case, we will tell you why.

**Research Funding**

This research is supported by the Health Research Council of New Zealand (HRC).

## Confidentiality

If you agree to take part in this study, the information obtained will be shared amongst investigators within the Department of Intensive Care, and the Centre for Bioengineering, University of Canterbury. However, no sensitive information will be collected, discussed or shared even amongst the research team. Only information that is directly relevant to this study will be used.

On any documents relating to the study, only a study code, or local ICU admission number, will identify them. Your National Health Information (NHI) number or any personal details that could identify you will not be used. You will not be personally identified in any reports on this study. Your medical information will be processed on a computer and held for up to 20 years. Study information will be kept secure. De-identified information may be shared amongst other researchers in this field. Results of this study will be presented at conferences and submitted for publication in medical and bioengineering journals. By signing the accompanying form, you agree to participate in this research, the record review, information storage, and data transfer described above.

**Contact Details**

For more information about this study, please feel free to contact the people below. You are also welcome to discuss this study with any of the Intensive Care doctors. You may telephone the ICU staff at any time (day or night) if you have any important concerns.

***Health and Disability Services Consumer Advocate:***

If you, your relative, or friend have any queries or concerns regarding their rights as a participant in this study, they may wish to contact a Health and Disability Services Consumer Advocate:

Telephone (03) 377 7501 or 0800 377 766 outside Christchurch.

***Maori Health Support:***

Eru Waiti

Maori Health Services

Canterbury District Health Board

Telephone: (03) 364 0640 Ext 88797; Mobile: 027 382 6587

Email: [Eru.Waiti@cdhb.health.nz](mailto:Eru.Waiti@cdhb.health.nz)

***Intensive Care:***

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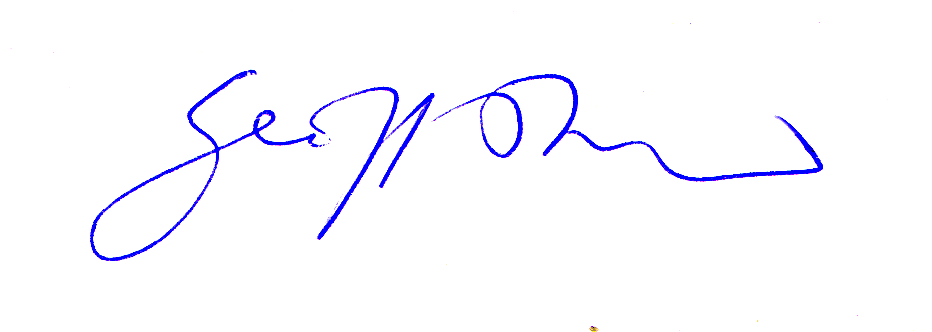
Email: [Geoff.Shaw@cdhb.health.nz](mailto:Geoff.Shaw@cdhb.health.nz)

Intensive Care Unit Reception:

Direct Dial: (03) 364 1077

This study has received ethical approval from the Southern Health and Disability Ethics Committee.

Thank you for considering participation in this study.



Geoff Shaw,

Co-ordinating Investigator