Information Sheet for Relative, Friend, Family/Whanau

Clinical Utilisation of Respiratory Elastance: the ‘CURE’ Study

-Optimising PEEP in people on mechanical ventilation

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| Co-ordinating Investigator |
| Professor Geoffrey M Shaw  Intensivist  Department of Intensive Care Medicine  Private Bag 4710. Christchurch Mail Centre 8140  Christchurch Hospital  Phone: (03) 364 1077 |

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| Co Investigators |
| |  |  |  | | --- | --- | --- | | Dist. Prof. J. Geoffrey Chase | Dr. Yeong Shiong Chiew |  | | Professor at University of Canterbury | Post Doctoral Researcher Fellow |  | | Department of Mechanical Engineering | Department of Mechanical Engineering |  | | University of Canterbury | University of Canterbury |  | | Phone: (03) 364 2987 ext 7224 | Phone: (03) 364 2987 |  | |

# Participation

Your relative or friend is being mechanically ventilated because their lungs are not working properly. They are invited to take part in a study called a Clinical Utilisation of Respiratory Elastance (CURE) randomised control trial (RCT). This study is trying to find out whether ICU doctors and nurses using a computerised method of adjusting the ventilator settings can improve the care of people in ICU.

Before you consider whether your relative or friend would want to take part in this study, 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 at any time.

## 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 participation in this study because they are ventilated and have been diagnosed with ARDS.

## The Study

Your relative or friend is currently being 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 overstretches 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.

Your relative or friend may be 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 your friend or relative is in group A) they will receive usual ventilation care by ICU doctors and nurses. A computer will record the information from the ventilator, but this will not influence their care.

If your friend or relative is in group B) **a computer will record the information from the ventilator and recommend the best PEEP setting on the ventilator**. The doctors will use the PEEP calculated by the computer setting if they think it will help your relative’s or friend’s care. Their lung “stiffness” will change over time, so we will also check the lung stiffness at regular intervals and each time they are turned in bed. The PEEP settings will be adjusted as necessary.

### Risks

There is a small risk that the PEEP setting suggested by the computer might not be the most suitable for your relative or friend. This risk is minimised by asking the doctor if they agree with the PEEP level suggested by the computer. If the ICU doctor is not satisfied with the computer’s suggestion, they will choose another PEEP, which they consider more appropriate. The computer cannot adjust the PEEP itself; an ICU staff member must manually change this setting.

**Possible Benefits**

### Your relative or friend may or may not experience any benefits by taking part in this study. However, there will be more frequent attention paid to their ventilation and changes to the ventilator will be made more frequently, which may result in a faster recovery.

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

### Compensation

In the unlikely event of a physical injury as a result of your friends/relatives participation in this study, they 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 their case will need to be assessed by ACC according to the provisions of the 2001 Injury Prevention Rehabilitation and Compensation Act. If the claim is accepted by ACC, they still might not get any compensation. This depends on a number of factors such as whether they 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 your relative or friend has ACC cover, generally this will affect their 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

If your friend/relative takes part in this study, you are always free to offer your opinions about their ongoing participation at any time, without having to give a reason. This will not affect their continuing health care.

Your friend’s/relative’s doctors may stop this study, or their participation in this study, at any time, for any reason, without seeking your opinions. If this happens, it might be because their condition has changed, or because of technical problems relating to the equipment.

# Investigator Payment

The investigators are not paid for this study.

## Confidentiality

If you agree to your relative or friend taking 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. Their National Health Information (NHI) number or any personal details that could identify them will not be used. They will not be personally identified in any reports on this study. Their 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 consider your friend or relative would agree to participate in this research, the record review, information storage, and data transfer described above.

**Research Funding**

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

**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:***

Prof Geoffrey M Shaw (Co-ordinating Investigator)

Department of Intensive Care

Christchurch Hospital

Private Bag 4710

Christchurch 8011

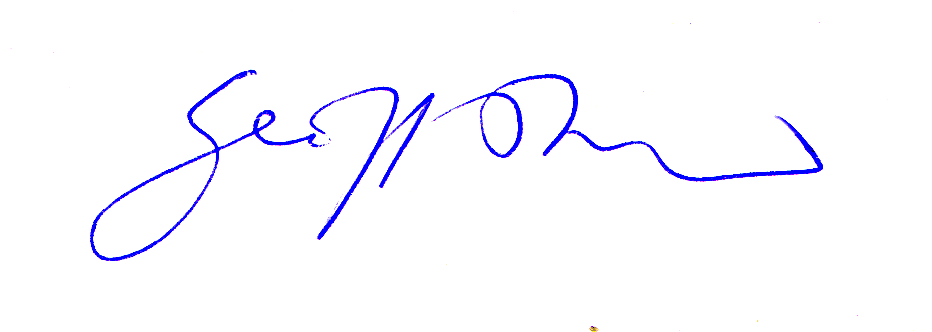
Email: [Geoff.Shaw@cdhb.health.nz](mailto:Geoff.Shaw@cdhb.health.nz)

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 your relative or friend’s participation in this study.



Geoff Shaw,

Co-ordinating Investigator