STATEMENT BY RELATIVE/FRIEND/FAMILY/WHANAU

**Clinical Utilisation of Respiratory Elastance (CURE) Trial**

**-Optimising PEEP in mechanically ventilated patients**

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| --- | --- |
| Lay title: | Optimising PEEP during mechanical ventilation |
|  |  |
| Co-ordinating investigator: | Prof. Geoffrey M Shaw |
|  |  |
| Participant’s name: |  |

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| --- | --- | --- | --- |
| English | I wish to have an interpreter | Yes | No |
| Deaf | I wish to have a NZ sign language interpreter | Yes | No |
| Māori | E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero | Ae | Kao |
| Cook Island Māori | Ka inangaro au i tetai tangata uri reo | Ae | Kare |
| Fijian | Au gadreva me dua e vakadewa vosa vei au | Io | Sega |
| Niuean | Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu | E | Nakai |
| Sāmoan | Ou te mana’o ia i ai se fa’amatala upu | Ioe | Leai |
| Tokelaun | Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika | Ioe | Leai |
| Tongan | Oku ou fiema’u ha fakatonulea | Io | Ikai |

I have read and I understand the information sheet dated 4th September 2014 for people taking part in the randomised control trial designed to optimise PEEP in mechanically ventilated patients in ICU. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use family/whanau support or a friend to help me ask questions and understand the study.

I believe that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (participant’s name) would have chosen and consented to participate in this study if he/she had been able to understand the information that I have received and understood.

I understand that taking part in this study is voluntary and that my relative/friend may withdraw from the study at any time if I or he/she wishes. This will not affect his/her continuing health care.

I understand that his/her participation in this study is confidential and that no material which could identify him/her will be used in any reports on this study.

I understand that the study will be stopped if it should appear to be harmful.

I understand the compensation provisions for this study.

I know whom to contact if anything occurs that might make my relative/friend consider withdrawing from the study.

I know whom to contact if I have any questions about the study.

This study has been given ethical approval by the Southern Health and Disability Ethics Committee. This means that the Committee may check at any time that the study is following appropriate ethical procedures.

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| Date: | / / 201\_\_ |
|  |  |
| Signature: |  |
|  |  |
| Printed name: |  |
|  |  |
| Relationship to participant: |  |
|  |  |
| Address for results: |  |
|  |  |
| Full names of researchers: | Prof Geoffrey M Shaw  Dist Prof J Geoffrey Chase  Dr Yeong Shiong Chiew |
|  |  |
| Contact phone number for researchers: | (03) 364 1077 |
|  |  |
| Project explained by: |  |
|  |  |
| ICU position or project role: |  |
|  |  |
| Signature: |  |
|  |  |
| Date: | / / 201\_\_ |

**STATEMENT BY CO-ORDINATING INVESTIGATOR**

I, Prof. Geoffrey M Shaw declare that this study is in the potential health interest of the group of patients of which \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(name of participant)* is a member and that participation in this study is not adverse to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(name of participant)*’s interests.

I confirm that if the participant becomes competent to make an informed choice and give an informed consent, full information will be given to him/her as soon as possible, and his/her participation will be explained. If the participant makes an informed choice to continue in the study, written consent will be requested and if the participant does not wish to continue in the study, he/she will be withdrawn.

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| Signed: |  | Date: |  |
|  | (Co-ordinating Investigator) |  |  |

**(If applicable at a later stage)**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(participant)* have read the information sheet for participants in the study “*Clinical Utilisation of Respiratory Elastance (CURE) Study: Optimising PEEP in mechanically ventilated patients*”. I have had the opportunity to ask questions so that I can be fully informed about this study agree to continue taking part in it.

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| II wish to receive a copy of my results. |  | Yes |  | No |
|  | | | | |
| II wish to receive copies of scientific publications from this study. |  | Yes |  | No |
|  | | | | |
| II agree to my GP being informed of my participation in this study. |  | Yes |  | No |
|  | | | | |

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| --- | --- | --- | --- |
| Signed: |  | Date: |  |
|  | (Participant) |  |  |