**PERSON RESPONSIBLE INFORMATION AND CONSENT FORM**

observational cohort study.

**Principal Researcher:**

Dr Elizabeth Skinner
Senior Intensive Care Unit Physiotherapist
Western Health

**Researchers at Peninsula Health**

Associate Professor Ravi Tiruvoipati, Intensivist, Intensive Care Unit, Peninsula Health

Mr Michael Wang, Physiotherapist, Peninsula Health

**Introduction**

As the ‘person responsible’ for the patient, you are invited to consider the patient’s participation in this research project. Victorian law allows the person responsible for a patient to consent to the patient taking part in medical research where the patient is unable to provide consent for themselves.

The patient is invited to take part in this research project. This is because the patient has come into the intensive care unit needing the support of a breathing machine and is likely to stay in the intensive care unit for at least 5 days. This research project is looking at improving outcomes for clients who need the support of a breathing machine and likely to require a stay in intensive care unit for 5 days or more. This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you think the patient would be willing 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 healthcare worker. Participation in this research is voluntary. If you think the patient wouldn’t wish to take part, you don’t have to consent. The patient will receive the best possible care whether you take part or not. If you decide you want the patient to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read;

• Consent for the patient to take part in the research project;

• Consent for the use of the patient’s personal and health information as described;

• Consent for the patient to participate in the research processes that are described.

You will be given a copy of this Participant Information and Consent Form to keep.

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

Currently, we know that patients in the intensive care unit are at a higher risk of being deconditioned and have worse quality of life even up to one year after leaving ICU. A quarter of these patients suffer a severe weakness syndrome defined as ICU-acquired weakness (ICU-AW). This results in significant limitations to people being able to perform their usual activities required for living (e.g. standing, walking, brushing teeth, showering or feeding themselves).

The specific cell-level interactions that influence this weakness syndrome are yet to be fully understood. The protein activin limits muscle growth and causes severe muscle wasting. Activin has been shown to be in high levels in people with critical illness who have infection, however the effect this has on muscle mass and weakness has not been established in this setting. The project aims to investigate the association of activin levels with muscle strength and function in ICU patients.

This study is being run at Frankston Hospital and Western Hospital. We aim to have a total of 20 participants. This research has been initiated by our principal investigator, Dr Elizabeth Skinner. This research is being conducted at Western Hospital and Frankston Hospital and is being funded by a Western Hospital Research Grant. This is a pilot study, depending on the result of this study, the result of this research could be used justify the need for a larger study.

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

Participation will involve assessment of the patient’s strength and ability to mobilise whilst in hospital. This is part of their normal care. We will also collect a small blood sample to measure the levels of a protein called activin. A very small amount is required (1-2 mL).

**What are the possible benefits?**

It is likely that the findings from this research may not benefit the patient directly. We will however provide you with detailed information on their study results, which may be of interest to them as these results may indicate their recovery from the physical weakness which may result from their critical illness.

These results will also be added to your medical records at Western Health and Peninsula Health as they may be useful in their future health care.

**What are the possible risks?**

The blood samples required are very small in size, 1-2 mL each time. The patient will have lines in their body as a part of usual care so the samples will be taken easily. The amount is very small so the risk to them is minimal.

The exercise testing may cause some discomfort as the patient may be deconditioned, however the tests only require them to do their best. As already mentioned, these tests and strength measures are usually part of their care and so they will complete these whether they are in the project or not.

**What if new information arises during this research project?**

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects the patient.

**Are there alternatives to participation?**

Participation in this research is not the patient’s only option. You do not have to agree to the patient participating in this research project. If you decide not to let the patient participate, the patient will continue to receive appropriate physiotherapy, medical and nursing care.

**Does the patient have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish the patient to take part they don’t have to. If you decide to let the patient take part and later you change your mind before the patient has been asked for continuation of consent, you are free to withdraw the patient from the project at any stage. Your decision whether to let the patient to take part or not to take part, or take part and then withdraw, will not affect the patient’s physiotherapy care or their relationship with those treating the patient or the patient’s relationship with Western Health or Peninsula Health.

**What if I wish to withdraw the participant from this research project?**

If you decide that the patient should leave the project before the patient has been asked for continuation of consent, the researchers would like to keep the personal and health information about the patient that has been collected. This is to help them make sure that the results of the research can be measured properly.

If you decide to withdraw the patient from the study before the patient has been asked for continuation of consent, please notify a member of the research team before you withdraw your consent. This is because we need to clarify whether you are happy if we continue to use the data we have already collected as part of our research study.

**How will I be informed of the final results of this research project?**

At the completion of the project, you or the patient if they have provided continuation of consent will receive a lay summary of the project and its results by post.

**What will happen to information about the patient?**

Any information obtained for the purpose of this research project that can identify the patient will be treated as confidential and securely stored. Once the data is collected and put into storage it will be de-identified. Any physical data will be locked up and electronic data will be password protected. The information will only be used for the purpose of this research project and only accessible to those involved in conducting the project. The information will be kept for 7 years after the completion of the project. After this time, all data will be disposed of appropriately (i.e. shredded or deleted). It will be disclosed only with your permission, or as permitted by law.

In any publication and/or presentation, information will be provided in such a way that the patient cannot be identified, except with your permission. All data published will not be identifiable.

Information about the patient’s participation in this research will be recorded in their health records.

**Can I access research information kept about the patient?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about the patient. Please contact one of the researchers named at the end of this document if you would like to access the patient’s information.

In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years. You must be aware that the information collected about the patient may at some point not be able to be identified once the identifying information has been removed after 30 days. Access to information about the patient after this point will not be possible.

**What happens if the patient is injured as a result of participating in this research project?**

If the patient suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to the patient if you elect the patient to be treated as a public patient.

**Is this research project approved?**

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. This study has been reviewed and approved by Monash Health Human Research Ethics Committee and also authorised to commence at Peninsula Health.

**Person Responsible Consent**

I have read, or have had read to me in a language I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I am the Person Responsible for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I consent to the ongoing participation of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in the research project named above, according to the conditions outlined in this document.

I believe that the carrying out of the procedure is not contrary to the best interests of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

I give permission for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Peninsula Health concerning \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_’s disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that I will be given a copy of the Person Responsible Information and Consent Form to keep.

I consent to the Participant’s data being used in future research that has Yes ☐ (please initial)

been approved by the Human Research Ethics Committee. No ☐ (please initial)

Participant’s name (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Responsible (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_

Witness to signature (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the person named above as the Person Responsible has understood that explanation.

Researcher’s name (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_

**Who can I contact?**

The person you may need to contact will depend on the nature of your query. Therefore, please note the following.

**For further information:**

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the principal researcher:

Name: Dr Elizabeth Skinner OR Name: Mr Michael Wang

Position: Principal Researcher Position: Physiotherapist, Peninsula Health

Telephone: 0419 101708 Telephone: 9784 7655

**Complaints:**

If you have any questions or concerns about your rights as a participant in this study, or if you have any complaints you may contact:

Name: Ms Deborah Dell

Position: Manager, Human Research Ethics Committee, Monash Health

Telephone: 03 9594 4611

Or at Peninsula Health

Manager

Research Program

Telephone: 9788 1473

Email ResearchEthics@phcn.vic.gov.au