Canterbury
District Health Board
Te Poari Hauora ō Waitaha

Information and Consent Form
August 2018

Is there a relationship between processed EEG characteristics during anaesthesia and general level of health?

Principal Investigator:
Associate Professor Dr Ross Kennedy, Specialist Anaesthetist, Christchurch Hospital, Christchurch
Telephone: 03 364 0288
Study Co-ordinator: Margie McKellow

Statement of Approval
This study has been approved by the Northern A Health and Disability Ethics Committee and by the Clinical Director, Department of Anaesthesia, Christchurch Hospital.

Please feel free to contact the researchers if you have any questions about this study.

Introduction
This information and consent form is **3** pages long. Please make sure you have all the pages.

Your consent
You are invited to take part in a study to help us find out whether there is a link between EEG (brain) 'energy' and general level of health. You will only be invited to take part in this study if it is safe and appropriate for you and your type of surgery.

About the study
EEG monitors are being used more and more during anaesthesia to reduce the risk of awareness and to allow the anaesthetist to give an anaesthetic more specifically targeted to each individual patient. It is recognised that the EEG activity during anaesthesia becomes less energetic with age, and we have also observed differences in the energy of the EEG between patients of similar age that appears to relate to their overall level of health.

It is well-recognised that how fit someone is before their operation has an effect on recovery after surgery. We want to find out if there is a relationship between someone's general physical fitness and the amount of EEG activity. If we confirm that these two are related, we may be able to able to use this to predict how a patient is likely to recover, both mentally and physically, after their operation and put measures in place to optimise this.

So what will be different about my procedure?
Your actual anaesthetic care will be the same as if you were not taking part in the study. However, before your surgery we will ask you some questions to give us an idea of how your current health has affected you both physically and mentally over the last month. We will also ask you to do a simple 'get up and go' assessment in which you get up from a chair, safely walk three metres and return to your chair. We will time how long this takes.
The day after your surgery we will visit you in hospital to ask you a few questions about how you are feeling, and we will telephone you around a month later to ask some questions about your recovery.

Monitoring

You will have standard anaesthetic monitoring, including the EEG monitor, from which our system records the data and collects it automatically onto a computer.

We will use this information for the study and will keep the data in a form which does not identify you. If there is any reason either before or during your surgery to deviate from the study protocol, your anaesthetist will do so.

Compensation provisions

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You would have to lodge a claim with ACC and if your claim is accepted, you will receive funding to assist in your recovery.

Participation

Taking part in this study is entirely your choice. You do not have to take part and if you choose not to, your care will not be changed in any way. You are also free to withdraw from the study at any time and this will in no way affect your anaesthetic or other health care.

What will happen at the end of the study?

It is expected that the results of this study will be presented at Anaesthetic meetings and in Anaesthetic publications.

Confidentiality

No material, which could personally identify you will be used in any reports on this study. You will be assigned a study number, and all data will be analysed under that number. Data from the study must be stored for up to 10 years and we may use this information in future studies.

Where can I get more information about the study?

You can get further information about the study by contacting the Principal Investigator or Research Co-ordinator at the Department of Anaesthesia, Christchurch Hospital on 03 3640288:

Dr Ross Kennedy	*Specialist Anaesthetist, Principal Investigator, Christchurch*
Margie McKellow	*Research Co-ordinator, Christchurch*

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact a Health and Disability Service Consumer Advocate, telephone (03)377 7501 or 0800 377 766 outside Christchurch. For Maori cultural support, you can contact Nga Ratonga Hauora Maori Health Service, 42 Stewart Street, telephone: (03) 3640 640, ext 86160.

Results

If you wish, you can be sent a summary of results of this study. You can tick this option on the Consent Form. There may be a delay of a year or two from the end the study to the publication of results.

Consent Form

Is there a relationship between processed EEG characteristics during anaesthesia and general level of health?

- I have read and I understand the information sheet dated August 2018 for volunteers taking part in the study exploring the relationship between EEG activity, fitness levels and recovery outcomes
- I have had the opportunity to discuss this study and I am satisfied with the answers I have been given
- I understand that taking part is my choice and that I may withdraw from the study at any time and this will in no way affect my anaesthetic care
- I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study
- I understand that data collected as part of my normal anaesthetic care will be kept in a form that does not identify me and may be used for further related studies
- I understand the compensation (ACC) provisions for this study as outlined under 'Compensation'
- I have had time to consider whether to take part and I know whom to contact if I have any questions about the study.

Please circle: **YES / NO**

I wish to receive a copy of the results when they become available YES / NO

I (full name)_____ hereby consent to take part in this study.

Signature: …… Date: ……

Names of Researchers: Ross Kennedy, Margie McKellow
Contact Number for Researchers: (03) 364 0288

Project Explained By: Margie McKellow ☐ *or* Other ☐
Project Role: Research Co-ordinator ☐ Researcher/Summer Student ☐ *or* Other ☐ *(Please specify):*
Signature:
Date:

(Note: A copy of the consent form is to be retained by participant and a copy to be placed in the medical file.)

Should you request a copy of the Study results, please write your address below:

Name: _____
Street Address: _____

Suburb: _____

City: _____ *Post Code:* _____

Thank you for agreeing to take part in this study.