**AUCKLAND CITY HOSPITAL**

Department of Anaesthesia & Perioperative Medicine

Private Bag 92024

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**Information Sheet**

**Study Title: The Influence of Anaesthetic Depth on Patient Outcome after Major Surgery**

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| **Principal Investigator:** | Assoc Professor Timothy Short |
| **Address:** | Department of Anaesthesia,  Level 8, Support Building,  Auckland City Hospital,  Auckland. |
| **Phone number:** | 09 375 7095 |

We would like to ask you to think about taking part in a study that looks at your brain waves during surgery.

We are looking to see if there is any difference in how you recover based on brain wave activity in relation to your anaesthetic. While you are asleep, we observe and monitor your brain activity using bispectral index monitor (BIS monitor).The BIS monitor and similar monitors are used in everyday practice during surgery across New Zealand and worldwide. We are not testing anything new.

We are looking at patients who are aged 60 years and older who have some medical problems and whose surgery and anaesthetic lasts around 2 hours in length.

If you do decide to take part we will ask you to sign the patient consent at the end of this document, we will give you a copy for your records and one kept in your clinical notes.

**Background**

Worldwide, millions of patients have surgery and have post-operative complications. No one knows why one person might stay in hospital longer then another, or why someone takes longer to shake off the effects of their anaesthesia (feeling tired, restless, confused). This study will enrol 6500 patients internationally with the aim of answering some of these questions.

The study randomly allocates participants to one of two groups. By using the BIS monitor and asking the anaesthetist to keep your brain waves within a certain range we can check to see if one group recovers better. The two groups are within the ranges of normal practice. Everything else about your surgery and care will remain the same.

**What does the study involve?**

Before and after surgery we ask you to answer some health related questions; such as how far you can walk or how easily you can do your daily tasks without problems in relation to your surgery. We gather all the usual information from your medical notes; such as age, height weight and medical history. This helps us work out if some patients are at more risk of postoperative complications.

While you are in hospital, a member of the research team will visit you and look over medical notes to see how you are doing.

At 30 days and 1 year after surgery, we will call you to check on how you have been during that time, and if you have had any complications or admissions to hospital. Sometimes we need to contact your GP to confirm complications or if we were unable to contact you at either of these times.

Some of the doctors involved with the Balanced Study start to wonder about different things they might be seeing in their own practice and ask the teams who are running Balanced to collect some extra information. This does not change the main study. These studies are called sub-studies. If you are having surgery at a hospital that is involved in one of the sub-studies you may asked to take part in these. The sub-studies are completely optional and you can still be part of the main study even if you are not interested in the sub-studies.

***Sub-Study 1 – Post-operative confusion:***

In the days following your surgery one of the research team will ask you a few extra questions that are designed to identify any confusion that may not be immediately obvious.

***Sub-Study 2 – Increased BMI index:***

We will document weight, height, girth and neck measurements to see if there is any link between outcomes and body mass indicators.

**What are the possible benefits of taking part?**

While we intend that research increases knowledge and improves care, it may not be of any direct benefit to you.

**What are the possible risks and disadvantages of taking part?**

The risks of taking part in the study are the same as those faced by any patient receiving a general anaesthetic. Your anaesthetist will discuss these with you prior to your surgery.

*There are no extra risks associated with this study.*

**Other Treatments whilst on Study**

This study has no impact or restriction on any treatments or care you would normally receive.

**Alternatives to Participation**

Taking part in the study is voluntary and does not affect your normal care which may include using the BIS monitor during surgery.

**What if I withdraw from this research project?**

Your continued participant in this research study is entirely voluntary (your choice) and you are free to withdraw at any time, without having to give a reason. This will not adversely affect your continuing health care.

If you withdraw from the study, we would like to ask for your agreement to keep and analyse information collected up to the time you withdraw your consent.

**Termination of the Study**

It is unlikely that this research project will stop unexpectedly; however if it does you will be told the reason why.

**What happens when the research project ends?**

We plan to make available a report of our results at the end of this study, which we can provide to you on request. We plan to publish this information publicly in a widely read scientific medical journal.

**Confidentiality**

If you agree to take part in this study, the information obtained could be shared with the BALANCED study management team committee, the ethics committee, the regulatory authority or their approved representative and similar agencies in New Zealand, all of whom would have restricted access to your medical notes to verify the information gathered. Medical records that contain your identity will be treated as highly confidential and will be shared only with these agencies, or as required by law.

Data needed for the study will be copied from your medical records and entered into a secure database. On the study record and all other documents relating to the study, only a study code number or participant identification number (PIN) will be used to identify you. A **confidential** log will be kept linking which PIN is yours (for example; John Jones study ID 25001). Nothing that identifies you will be used in any reports or presentations.

There are no changes to the way that your medical information is stored or processed. Study specific information will be kept in a securely locked room in the department of anaesthesia and confidentially destroyed after 15 years. You have a right to see your personal information and correct it if necessary. You have the right to ask the study doctor about the data that has been collected already and that is being collected and why it is needed. Your GP will be sent a letter to tell them we enrolled you in the study. By signing the consent form you are agreeing to our continuing to review you medical notes and the collection and storage of study information as explained above.

**Compensation**

If you were injured in this study, which is very unlikely, you would be eligible to apply for compensation from ACC just as you would if you were injured in an accident at work or at home. This does not mean that your claim will be automatically accepted. You will have to follow the same process as normal and lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist with your recovery. If you have any questions about ACC, contact your nearest ACC office or the investigator.

#### Where can I get more information about the study?

You can get further information about the study by contacting the Principal Investigator or Research Nurse.

*Dr Timothy Short Principal Investigator*

*Davina McAllister Research Nurse Specialist*

If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an Independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act:

Telephone (NZ Wide): 0800 555 050

Free Fax (NZ Wide): 0800 2787 7678 (0800 2 SUPPORT)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

If you require Māori cultural support, talk to your whānau in the first instance.

Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext. 2324

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 486 8920 ext. 3204

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)

**STATEMENT OF APPROVAL**

This study has received ethical approval from the Northern A Health and Disabilities Ethics Committee Ref: *12/NTA/16* and institutional approval from the Auckland District Health Board (ADHB) Research Review committee. Site Ref: A+5015

Please feel free to contact any of the research team if you have any questions about this study.

***Thank you in advance for your help with this study***

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**Patient Information and Consent Form**

**Study Title: The influence of anaesthetic depth on patient outcome after major surgery**

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| --- | --- |
| **Investigator Name:** | Dr Timothy Short |
| **Investigator Address:** | Department of Anaesthesia,  Level 8, Support Building  Auckland City Hospital  Private Bag 92024  Auckland |
| **Phone number:** | 093670000 ext 25700 |

**Declaration by Participant**

* I have read and understood the information sheet dated 28th June 2016 for the volunteers taking part in this study evaluating the anaesthetic depth on patient outcome after major surgery.
* I have had an opportunity to discuss this study ask questions and I am satisfied with the answers I have received.
* I understand the contents of the information sheet including but not limited to, the following points:
* I understand that my participation in the study is confidential and that no material which could identify me will be used in any reports or presentations on this study.
* I understand that taking part in the study is my choice and I can decide to withdraw at any time if I wish. This will not affect my continuing health care.
* I understand that data has already been collected and I am giving my consent for the use of this data and for on-going participation and follow-up.
* I know whom to contact if I have any questions about the study.
* I understand that I will be given a signed copy of this document to keep.
* I understand that an approved auditor or their representative of the BALANCED Study Committee, the ethics committee or a regulatory authority may review my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
* Northern A Health and Disabilities Ethics Committee have given ethical approval to this study. The committee may check at any time that the study is following appropriate ethical standards and international guidelines.
* ADHB research review Committee has given institutional approval to this study. The committee may check at any time that the study is following all Good Clinical Research Practices as required by nationally and internationally regulations.
* I wish to receive a copy of the published results when it is finished YES/NO
* I consent to my GP being contacted about my involvement in this study YES/NO
* I would like to take part in the Delirium sub-study YES / NO/NA
* I would like to take part in the BMI Index sub-study YES / NO/NA

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|  | | | | | | |
|  | Name of Participant (please print) print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

Date

**Declaration by Study Doctor/Research Nurse Specialist**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Research Nurse Specialist (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

***Thank you for offering your consent to participate. A copy of the information sheet and consent form will be provided to you, and copies filed in your clinical notes.***

Note: All parties signing the consent section must date their own signature