Provision for follow-up information and consent form

Lay title:	MAnagement of Systolic blood pressure during Thrombectomy by Endovascular Route for acute ischaemic STROKE (MASTERSTROKE Trial)		
Short title	MASTERSTROKE		
Locality:	**Auckland City Hospital**	Ethics committee ref:	**19NTB163**
		Local Project number:	**ADHB 8173**
Lead investigator:	**Dr Douglas Campbell**	Contact phone number:	**3757095**

You were recently admitted to Auckland City hospital because you had a clot blocking the blood flow in your brain this needed to be removed urgently. At this time doctors involved in your care thought it was in your best interest to be involved in the Masterstroke study which compares two ranges of blood pressure management during clot retrieval. Due to the clot in your brain causing lots of different problems it was believed that you could not make an informed decision about taking part in the study. This document explains what being involved meant at the time of your enrolment in the study and what is involved for you now. After reading through this document and discussing the information so that you feel you understand everything we would like to ask you to sign a consent form agreeing to the being followed up by the research team until you reach day 90.

Why were you enrolled in the study?

When the doctors removed the clot that was blocking the blood flow to your brain you required a general anaesthetic. As part of the anaesthetic the doctors (anaesthetists) manage your blood pressure. For this study we are comparing two ranges of Systolic Blood Pressure (SBP) management to see if there is a difference in how you recovered after the stroke. We have called these two levels "standard" 140 mmHg +/- (130-150mmHg) and "augmented" 170mmHg +/- 10 (160-180mmHg).

What has happened so far with your involvement in this research study:

Because you were not are not able to provide your own informed consent at the time you were admitted to hospital we have been given approval by the reviewing ethics committee to ask the doctors involved in your care to decide on your behalf if enrolment (also called 'randomisation') into this study would be in your best interests.

Following an assessment to decide if you were eligible to participate in the study we consulted with your medical team who agreed that at the time of your hospital admission your participation in the study was in your best interest. Your doctor could, at any time, decide whether it was safe for you to continue in the study and withdraw you if necessary. We asked another doctor not directly involved in the study to confirm that participation in the study was in your best interest. The agreement to enrol you in the study has been documented in your medical notes prior to any study-specific procedures being performed.

We also discussed the study briefly with your family/Whanau prior to your enrolment. We did not ask them to decide on your involvement in the study because this can be a very stressful time and a lot of information is being given to them.

This research project is a randomised, controlled trial. You had a 50/50 chance of being allocated to receive either of the Systolic Blood Pressure (SBP) ranges explained below. We do not know which treatment is best for improving patient outcomes after a stroke, and the design of the study makes sure we are comparing the groups equally. Neither you nor the research team have been or will be told which treatment you received.

At the time of randomisation you received either

- 'Standard' – maintain SBPat 140+/-10mmHg from the start of anaesthesia until return circulation after removal of clot.

- 'Augmented' - maintain SBP at 170+/-10mmHg from the start of anaesthesia until return circulation after removal of clot.

To maintain the target SBP of the group you were put in to, we asked the anaesthetist to be extra vigilant at staying within the range and they could do this by using their normal standard of care. We recorded what medications they gave, including fluids and other anaesthetic drugs.
Now that you are well enough to make an informed decision, we are asking you to consider your ongoing involvement in the study and have given you with this information sheet to read over and discuss with your family. If you are happy for us to keep following you up and collect information about your recovery, we will ask you to sign the consent page at the end of this form. If you decided that you do not want to be involved any further, you can say NO and we will withdraw you from the study at this time. Your normal clinical care and follow-ups will continue and will not be effected by your decision.

What now:
You are now in the follow-up phase of the study; this means we are collecting information on how you recover.

Follow Up
Along with the normal care provide by the stroke team a research nurse will visit you regularly until you are ready to go home. We will give you or your family a call to check on your recovery at Day 90 (3 months) after your clot was removed. Before calling, we will check your medical records to see if you have had any complications that meant you were readmitted to hospital. If you are still in hospital we will visit you on the ward to see how you are doing.
If we are unable to contact you, we will check with your other doctors for this information.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid.

It is desirable that your local doctor be advised of your decision to participate in this research project.

Other relevant information about the research project
In total there will be up to 550 participants taking part in the study.

What are the alternatives to participation?
You have already received the study intervention and are now in the follow-up period. All clinical treatment you are receiving is standard of care.

You can decide that you do not wish to continue in the study at any time without having to give a reason. This will not affect your care or ongoing relationship with Auckland City Hospital.

Should you decide to withdraw from the study, we would like to ask you to consider allowing us to use your data that has already been collected, this is so that we can compare how everyone has recovered.

What are the possible benefits of taking part?

Now that you are in the follow-up part of the study all care you are receiving is standard of care. At the time of the clot retrieval, stricter blood pressure management was followed as part of the study so that we could compare how patients recovered. We cannot guarantee that there was a direct benefit to you; however, we believed that it was in your best interest to be involved as tighter blood pressure management has been linked to better outcomes for patients.

What are the possible risks and disadvantages of taking part?

There are no added risks or disadvantages to being involved in the study.

Termination of the Study

It is unlikely that this research project will stop unexpectedly.

What happens when the research project ends?

When the research project ends the study data will be analysed, this can take up to six months after the last patient recruited completes their 90 day follow-up. Once the results have been analysed a summary of the results will be available and can be sent to you if you would like a copy.

Confidentiality

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 identify you. A **confidential** log will be kept linking which PIN is yours (for example; Jane Jones, study ID 25001). Nothing that identifies you will be used in any reports or presentations.

If you agree to take part in this study, the information obtained could be shared with the MASTERSTROKE 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.

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 10 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 Doug Campbell	Principal Investigator
Ms 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@advocacy.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

STATEMENT OF APPROVAL

This study has received ethical approval from the Northern B Health and Disabilities Ethics Committee Ref: 19NTB163

This study has received institutional approval from the Auckland District Health Board (ADHB) Research Review committee. ADHB Ref: 8173

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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Declaration by Participant

- I understand that at the time of entering the study, I was unable to provide my own consent and my doctors were consulted to confirm that being in the study was in my best interest.
- I understand I can not withdraw my consent for enrolment in the study as this was never provided and that I am giving my consent to continue with follow-up and ongoing data collection and processing my information, including information about my health.
-
- I have read and understood the information sheet **Version 1_1 dated** 29th Oct 2019 for the volunteers taking part in the Masterstroke study.
- I have had an opportunity to discuss this study, ask questions and I am satisfied with the answers I have received. I have been given sufficient time to consider whether or not to participate in this study.
- 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 I can withdraw my consent to follow-up at any time and this will have no impact on my contunuing health care.
- 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 of the Masterstroke 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 B* 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 am aware that my GP will be sent a letter to let them know I am in the study.
- I wish to receive a copy of the published results when it is finished YES/NO

Declaration by participant:
I, the below named, hereby give my written consent to take part in the MASTERSTROKE Study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Provision for follow-up information – Withdrawal from Study

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Lead investigator:	**Dr Douglas Campbell**	Contact phone number:	**3757095**

Declaration by Participant

- I understand that at the time of entering the study, I was unable to provide my own consent and my doctors were consulted to confirm that being in the study was in my best interest.
- I understand I can not withdraw my consent for enrolment in the study as this was never provided and that I declining to continue with follow-up and ongoing data collection and processing my information, including information about my health.
- I am indicating below whether my data can be used or withdrawn.

☐ I would like the information collected about my involvement to be withdrawn study data.

☐ I would like the information collected about my involvement to be included in the study data.

Declaration by participant:
I, the below named, hereby withdraw consent to take part in the MASTERSTROKE Study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has withdrawn their consent to participate.

Researcher's name: _____

Signature: _____ Date: _____