



ASSENT FORM: participants 12-14 years old

HOME Brain Pressure Study Information Sheet

Study Title (lay): **HOME Brain Pressure study**
Sponsor: University of Auckland
Locality: Te Whatu Ora Te Toka Tumai (Auckland City Hospital)
Ethics committee ref.: 2024 FULL 18327
Lead Study Doctor: **Dr Peter Heppner**, Neurosurgeon Auckland City Hospital
Contact phone: 021 893 804
Lead researcher: **Sarah-Jane Guild** University of Auckland
Contact phone: 021 296 9030

You have hydrocephalus. Your brain doctor is going to help you by putting a tube to run from your head to your tummy that will drain the extra fluid that you have around your brain. We have made a new device, a sensor, that can measure brain pressure and we are inviting you to take part in testing of this sensor.

We want to find out if the sensor works well. It is important that you understand what is involved in taking part and the risks.

Your parent(s) / caregiver, study team and or surgeon will tell you more about being in this study.

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect your care.

If you agree to take part in this study, you will be asked to sign the last page.

WHY ARE WE DOING THIS?

The research team at the University of Auckland have made a new device that can measure the pressure in the brain.



WHAT IS THE PLAN?

Only If you agree to be involved: while the surgeon is putting the tube/shunt in your head, they will also put in a tiny sensor. It's small, about 3-4 grains of rice. It sits inside your head and cannot be

We want to find out if the sensor works well.

This is important because people with hydrocephalus can get headaches and feel bad when their shunt tube stops working. It can be hard to know when this is happening, so doctors often order tests.

This sensor could make it easier to tell if someone's shunt is working properly, so they don't have to come to the hospital as much. This would be a big relief for people with hydrocephalus and their families.

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seen from the outside. **It is important that you know that once the sensor is put in it can't be easily taken out, you would need another surgery.**

After surgery, while you are still in the hospital, we will teach you and your caregiver how to use the Wand to measure your brain pressure. This simply involves holding the Wand over where the device is in your head and holding the button while it gets a reading. This does not hurt at all. We will also give you a phone with a special app to track your headaches and other symptoms. The information you enter into the app will be shared with the research team and your doctor.

We are asking that you take a brain pressure measurement every day for the first two weeks after surgery and then every two days for 3 months. Each time you measure your brain pressure you will have to sit quietly for about 5 min before you take the measurement.



WHAT DOES THE SENSOR DO?

The sensor only measures your brain pressure when the Wand is close to your head and the button pressed. The Wand cannot measure anything other than brain pressure. The Wand cannot change the way you think or control you.

You don't have to change what you do in your life to be involved in this study.

WILL THIS HELP ME?

This study may or may not help you. We hope to learn things that may help people with hydrocephalus, similar to you.

If you agree to be part of this study we will also tell your family doctor (GP) that you are doing the study and about the sensor.

Your medical notes may also be looked at by other people who work at the hospital to check that the study is being carried out correctly.





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All information that is collected about you during the study will be kept strictly private. You will be given a number which will be used instead of your name on the study information.

Any information about you that leaves the hospital will have your name and address taken off so that you cannot be recognised from it, except for letters to your family doctor (GP).

WILL IT MAKE ME SICK?

We hope that you will not feel any different when you have the sensor in your head. The research doctors will see your brain pressure after you make a measurement. If they see something unexpected, they will contact your surgeon.

Someone will be available to help at **all times**.

WHAT IF THERE IS A PROBLEM?

If you are worried about anything to do with the study, please ask your doctor or nurse who will do their best to answer your questions.



WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you or your caregiver have any questions, concerns, or complaints about the study (at any stage), please contact:

Davina McAllister Study nurse
Auckland City Hospital
Ph 0274891940 or davinams@adhb.govt.nz

Sarah-Jane Guild Dept Physiology and Bioengineering Institute,
University of Auckland,
Ph 021 2969030 or s.guild@auckland.ac.nz

Dr Peter Heppner, Neurosurgeon, Department of Neurosurgery,
Te Whatu Ora Te Toka Tumai (Auckland City Hospital),
Ph 021893804 or pheppner@adhb.govt.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Email: advocacy@advocacy.org.nz

If you require Māori cultural support contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext. 42324

You can also contact the health and disability ethics committee (HDEC) that approved this study on email: hdecs@health.govt.nz



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HOME Brain Pressure Study Assent Form

Study Title (lay): HOME Brain Pressure study

Sponsor: University of Auckland

Locality: Te Whatu Ora Te Toka Tumai (Auckland City Hospital)

Ethics committee ref.: XXXX

Lead Study Doctor: Dr Peter Heppner, Neurosurgeon Auckland City Hospital

Contact phone: 021 893 804

Lead researcher: Sarah-Jane Guild, University of Auckland

Contact phone: 021 296 9030

Your Name: _____
(Full Name in BLOCK CAPITALS)

Your month and your year of birth: ____/____
(Month / Year)

Please circle all you agree with: _____

- Have you read this form (or has it been read to you)? Yes / No
- Has the study doctor explained this study to you? Yes / No
- Do you understand what this study is about? Yes / No
- Have you asked all the questions you want? Yes / No
- Are you happy to take part in this research? Yes / No

If any answers are “no” or you don’t want to take part, don’t sign your name!

If you do want to take part in this study, please write your name and today’s date below.

You will be given a copy of this signed form.

Your name: _____

Your signature: _____

Today’s date: _____

Your parent(s)/legal guardian have to sign the main informed consent form.

Statement of Person Obtaining Informed Assent

I, the undersigned, have fully explained the details of this research study to the participant named above.

Person obtaining Assent (Print name): _____

Signature: _____

Date: _____