**Participant Information Sheet**

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| **Protocol title:** | Magnetic Resonance Imaging (MRI) of Brain Motion as an Indicator of Raised Intracranial Pressure. |
| **Lay Study Title:** | MRI informed computational model for non-invasive detection of brain pressure  |
| **Sites:**  | Mātai Medical Research Institute, Gisborne; Gisborne Hospital, Gisborne; Eye Institute, Remuera; AucklandGreenlane Eye Clinic, Greenlane Clinical Centre; Auckland |
| **Co-ordinating Investigator** | Associate Professor Samantha Holdsworth |
| **Principal Investigators:** | Professor Helen Danesh-Meyer, Associate Professor Samantha Holdsworth, Dr Gonzalo Maso Talou |
| **Sub investigators:** | Jet Wright, Dr Dineo Mpe, Dr Matthew McDonald, Dr Eryn Kwon, Dr Miriam Scadeng, Dr Sari Mackenzie, Dr Alireza Sharifzadeh-Kermani, Dr Soroush Safaei, Paul Condron, Dr David Freschini |

 You are invited to take part this study.

This project is being carried out by an expert team from both the Mātai Medical Research Institute in Gisborne and the University of Auckland.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends.  We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide, you may want to talk about the study with other people, such as whānau, friends, or healthcare providers.  Feel free to do this.

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 the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study up to 2 weeks after your data has been collected.

If you agree to take part in this study, you will be asked to sign the Consent Form. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 11 pages long, including the Consent Form.  Please make sure you have read and understood all the pages.

## What is the purpose of the study?

Our aim with this project is to develop a way to diagnose high-pressure intracranial conditions and ultimately measure pressure inside your head without any invasive procedures.

Idiopathic intracranial hypertension (IIH) is a condition where the pressure around your brain increases, and we can't find a specific reason for it. It often leads to headaches, vision problems and if left untreated, vision loss, though this is a rare outcome.

To diagnose IIH or monitor your progress, we usually need to do some tests. This includes taking pictures of your head with a special machine called an MRI, and examining the nerves at the back of your eyes. In this case, we also perform a procedure called a lumbar puncture which is a medical procedure used to collect a sample of cerebrospinal fluid (CSF) from your lower back. Lumbar puncture works as both a way to test your CSF for any abnormalities as well as reduce the pressure and often alleviate headaches and other symptoms of IIH.

An MRI is a safe way to take detailed pictures inside your body without touching you. It uses magnets to create these images. We're particularly interested in a new method called amplified magnetic resonance imaging (aMRI), which helps us see tiny movements in the brain. In this project, we'll be using aMRI to observe how the brain changes before and after lumbar puncture.

## What will my participation in the study involve?

You qualify for participation in this study if you have been diagnosed with or are suspected to have IIH by your treating physician.

Should you choose to take part, you'll be required to sign a consent form. Subsequently, you'll be invited to the Mātai Medical Research Institute in Gisborne, where experienced doctors, in consultation with the research team, will conduct the following investigations:

* Amplified magnetic resonance imaging (aMRI): an MRI machine uses a very strong magnetic field as well as radio waves to create high quality images of your anatomy. This will provide a detailed image of your brain, encompassing both standard and experimental programs. The standard MRI protocol will take about 45 mins, the experimental sequence is expected to add an extra 10-15 minutes to the scan.
* Optic coherence tomography (OCT) The OCT machine looks like the machines doctors use to examine your eyes. It has a place to rest your forehead as well as your chin. During the scan, you'll need to focus on a coloured light. This helps keep your eye still during the scan. The OCT utilises a light beam to evaluate the thickness of your retina and optic nerve. The scan usually takes about 5 minutes per eye.
* Lumbar puncture: This medical procedure involves using a needle to collect a sample of cerebrospinal fluid (CSF) from your lower back. This procedure typically takes 30 minutes. You are asked to remain lying flat for 30 minutes after the procedure.

If you participate in this study, the study procedures will occur in the following sequence.

* 1. OCT scan.
	2. aMRI scan, which will include both standard and experimental sequences. These images will be reviewed by a radiologist to determine if it is safe to proceed with the lumbar puncture.
	3. lumbar puncture.
	4. Four to six hours after your lumbar puncture, you will undergo a follow-up OCT scan as well as another MRI scan.

OCT scan ( 10-15 min) aMRI ( 60 mins) lumbar puncture (30 mins) 4 to 6 hour wait Post LP OCT scan ( 10-15 min) Post LP aMRI ( 60 mins)

Where the study differs from your clinical care will be as follows:

* the specific (experimental) aMRI sequences, which examine brain movement.
* The secondaMRI which will occur 4-6 hours after the LP. This is estimated to extend the standard MRI scan time by approximately 10-15 minutes.
* The post lumbar puncture OCT scan

Participants from the Gisborne area:

We will coordinate a suitable time for you to undergo all tests during a single visit to the Mātai Medical Research Institute. Please note that the study visit is expected to take up to 8 hours.

Participants from Auckland:

The study programme will be:

1. Flight in morning ->Pre- LP aMRI + OCT -> LP ->Post-LP MRI + OCT -> Flight back at night.

OR

1. Flight in evening-> travel accommodation for the night ->(the next morning) Pre-LP MRI + OCT -> LP -> (4-6 hours later) Post-LP MRI + OCT -> Flight back at night.

OR

1. Flight in morning -> Pre-LP MRI + OCT -> LP -> Post-LP MRI+ MRI -> travel to accommodation for the night -> Flight back the next morning

This will depend on the timing of your flight and the availability of research staff. Please allow for the entire study visit to take up to 48 hours, although we will aim get you back in Auckland within 24 hours.

## What are the possible benefits and risks of this study?

While lumbar puncture is a generally safe procedure, there are some rare risks associated:

1. Post lumbar puncture headache:
- this is the most common complication occurring in about 1 in 4 patients. It can occur due to a leak of your cerebrospinal fluid from the puncture site. The headache typically starts a few hours after the procedure however, it can start several days after the procedure. This headache typically worsens when you are sitting up and improves when you are lying down. These headaches, while typically self-limiting, can be severe and can last for weeks.
2. Nerve damage:
- this can result in short or long term pain, pins and needles or a loss of feelings in your lower limbs
3. Back pain:
- Tenderness around the puncture site may occur.
4. Infection:
- There is a risk of introducing an infection into the puncture site or meninges ( meningitis). A sterile technique is used to minimize the chances of such occurring.
5. Bleeding/haematoma:
- Bleeding in and around the spinal cord can occur causing symptoms such as severe lower back pain, pain radiating down the legs, loss of sensation in the lower area and saddle, bladder and bowel dysfunction, weakness and paralysis of the lower limbs. Rarely, this constellation of symptoms can be an indication of a condition known as Cauda Equina Syndrome, where your nerves below your spinal cord are compressed. This a medical emergency that requires prompt surgical intervention.
6. Brain herniation:
- In people with increased brain pressure due to conditions such as brain masses/ tumours, a lumbar puncture can results in a life threatening shift of brain tissue. The pre-lumbar puncture MRI will assess for such causes. If the radiology team is not satisfied with your MRI scan we will not proceed with the lumber puncture.
7. Failure of procedure:
Sometimes it is too difficult to perform a lumbar puncture. IF this happens your primary treating team will be made aware and an alternative LP method will be organised if needed.

This procedure will be performed by an experienced anaesthetic specialist. If you are experiencing headaches related to IIH, lumbar puncture can provided relief for your symptoms.

Risks associated with aMRI

1. Allergic reaction to the contrast agent used to enhance the aMRI. These include but are not limited to:

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| --- | --- |
| Nausea | Swelling of the mouth and airways |
| Vomiting | Shortness of breath |
| Cardiovascular compromise | Dizziness |
| Rash | Wheeze |

1. Claustrophobia:
- Some people find being in confined spaces very challenging. The MRI machine is a narrow cylindrical tube that can induce anxiety and panic in people with claustrophobia. Please inform the research team if you are claustrophobic. They can provide additional supports and accommodations for you.

Medical personal will be onsite in case any issues arise during your MRI.

Risks associated with OCT:

Risks associated with OCT are minor. Occasionally, people experience temporary visual disturbances associated with a light flash that occurs during this imaging. This is very short lived ( usually less than 1 minute) and is not known to cause harm to your eyes or your vision.

During your visit, the healthcare professionals overseeing and performing the investigations will again provide comprehensive discussions regarding the particular risks and benefits associated with these procedures. This ensures that you have a clear understanding of what to expect and can make informed decisions about your participation.

## Who pays for the study?

This study is being funded by grants from the Marsden Fund as well as the Health Research Council of New Zealand ( HRC) .

Participants from the Gisborne area:

If you come in personal transport (driven by yourself, friends or whānau), you will be eligible for a petrol reimbursement for the session of 50 dollars. If you are unable to organise personal transport, Mātai will instead cover taxi fees. Refreshments as well as lunch will be provided by the institute.

Participants from Auckland:

Mātai Research Institute will cover your flights, all study-related travel in Gisborne, and, if necessary, accommodation in Gisborne. Additionally, a $150 per day koha/ allowance will be provided to cover food and other expenses during your time in Gisborne. If your stay in Gisborne is extended due to study-related processes, the institute will also cover any additional food, accommodation, and travel costs. You may travel with a support person if you choose, however, the institute will not cover their costs. It is important to note that flying can temporarily worsen IIH symptoms. Please inform the research staff if you have difficulties during your travels.

## What if something goes wrong?

If you are injured in this study, which is extremely unlikely, you would be eligible for compensation from ACC just as you would be if injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

## What information are you taking?

During the lumbar puncture, we will gather data on the pressure at both the outset and conclusion of the procedure. We will also be sending your CSF to the lab for analysis. The study will not collect the analysis of your CSF. Instead, the result will be sent to your treating team.

Regarding aMRI, we will capture images of your brain to examine its overall structure. Additionally, we will analyse any alterations in brain movement before and after the lumbar puncture. This allows us to observe any potential changes that may occur as a result of the procedure.

For the OCT, we capture images of your optic nerve before and after the lumbar puncture. We will collect routine demographic data including your age, gender, ethnicity. Additionally, we will collect routine observations such as your height, weight, blood pressure, and heart rate. By agreeing to participate, you also consent to grant researchers access to your medical records from the Eye Institute, Greenlane Eye Clinic and Gisborne Hospital to collect relevant study information such as your medical history and current medications.

## What will happen to my information:

Your identifiable data will be stored on a secure electronic data base hosted by the University of Auckland. Only researchers under the supervision of the principal investigators will have access to this data.

The results of your scans and lumbar puncture will be shared with your primary treating team, as they will ultimately use this information to direct your care. Once that has been communicated, your information will be coded with a reference number, a process known as de-identification. This reference number is used to de-identify all other data so that your identity is kept confidential. Your information will only be seen by you and the researchers and will be kept in a secure data storage location or filing cabinet. Only the few researchers who need to know your identity will have access to this. MRI data will be stored password-protected Mātai Medical Research Institute computers, and back-ups of raw MRI (de-identified) data will be stored in a server, managed by the Centre for eResearch of the University of Auckland for post-processing and analysis, to allow for publication and future re-analysis. This is to prevent any information leaking that could identify you, as we have no permission nor intention to allow any identifiable data to be accessed by the public or anyone analysing the data, hence why all your data will be de-identified. A database of de-identified MRI images will be created for the research team to analyse.

Data sharing encourages transparency in science and allows other researchers to make use of collected data. It is possible that other researchers may request the use of these data. With your permission, if such a request is received, your de-identified data will be shared in accordance with the Privacy Act 2020: only with the permission of the researchers, solely for the purpose of research, and only once it is ensured that none of the data can identify you (for instance, we will take additional steps to remove any potentially identifying information from the records, and to remove any external physical features captured by the MRI images in case these could be potentially identifying).

Any publications or presentations arising from this research will not contain any information that could personally identify you. Any publications arising from the work will be made available online, and where possible, we will alert you to this. Identifiable data will not go overseas.

Rights to Withdraw Your Information:

You may withdraw your consent for the collection your information at any time, by informing a member of the research team. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study may continue to be used and included in the study. If you wish to withdraw/ delete your information from the study, you can do so within two weeks of its collection. You can still request that your data be withdrawn beyond 2 weeks after its collection, however, it may not be possible to withdraw your data from the study as it may have already been analysed or published. Withdrawn data will not be used for future research.

Future research using you information:

If you agree, your coded information may be used for future research related to IIH. If you agree, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data. You will not get reports or other information about any research that is done using your information

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

## What are my rights?

If you do agree to take part, you are free to withdraw from the study at any time, even after it has started, without having to give a reason. There are no potential consequences of withdrawal from the study, and this will in no way affect you continuing or future care. However, it will not be possible to withdraw data from the study results if these have already been analysed or published. Withdrawing your data also means that it will not be used for future research purposes.

You have the right to access information collected about you as part of the study. All participants will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your health.

Ownership Rights:

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to the University of Auckland and Matai Medical Research Institute. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

## Who do I contact for more information or if I have concerns?

**We appreciate the time you have taken to read this information. If you have any questions,  concerns, or complaints about the study at any stage, you can contact:**

**Dr Samantha Holdsworth (Co-ordinating investigator)**

Mātai Medical Research Institute

466 Childers Road, Gisborne 4010

Ph: 021 834 164

Email: s.holdsworth@matai.or.nz

**Davidson Taylor (Māori Cultural Advisor)**

Mātai Medical Research Institute

466 Childers Road, Gisborne 4010

Ph: (06) 863 1425

Email: d.taylor@matai.org.nz

**Jethro Wright ( Sub investigator)**

Mātai Medical Research Institute

Ph: 027 351 4293

Email: j.wright@matai.org.nz

**Dineo Mpe ( Sub investigator)**

Eye Institute

Email: dineo.m@eyeinstitute.co.nz

Ph: 021 081 57 234

**Reweti Ropiha (Director Turanga Health)**:

CEO Turanga Health

Ph: (06) 869 0457

Email: admin@turangahealth.co.nz

**You can also contact the health and disability ethics committee (HDEC) that approved this study:**

Ph: 0800 4 ETHIC

Email:  hdecs@health.govt.nz

**Independent health and disability advocate:**

Ph: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@advocacy.org.nz Website: https://[www.advocacy.org.nz/](http://www.advocacy.org.nz/)

**Better Than A Hole In The Head? Magnetic Resonance Imaging (MRI) Of Brain Motion As An Indicator Of Raised Intracranial Pressure.**

**CONSENT FORM -** THIS CONSENT FORM WILL BE HELD FOR A PERIOD OF SIX YEARS

Researchers: Professor Helen Danesh-Meyer, Dr Samantha Holdsworth, Dr Gonzalo Maso Talou, Jet Wright, Dr Dineo Mpe, Dr Matthew McDonald, Dr Eryn Kwon, Dr Miriam Scadeng, Dr Sari Mackenzie, Dr Alireza Sharifzadeh-Kermani, Dr Soroush Safaei, Paul Condron, Dr David Freschini

* I have read the Participant Information Sheet, I have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have had them answered to my satisfaction.
* I understand the risks associated with lumbar puncture and agree to undergo this procedure.
* I agree to take part in this research.
* I am satisfied with the answers I have been given regarding the study.
* I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time without giving a reason.
* I understand that I can withdraw any of my data up until 2 weeks after it has been collected. Data withdrawn after this time may still be used for this study.
* I understand that my withdrawn data will not be used for any future research.
* I understand the risks associated with MRI.
* I understand that, in the MRI scanner, some people may feel claustrophobic, and may experience feelings of slight warmth, dizziness or peripheral nerve stimulation (like tickling) due to the magnetic field. If this occurs I can choose to cease scanning.
* I understand that the second MRI scan and second OCT scan of the optic nerve is for research purposes.
* I understand that there is a small possibility of “incidental findings” of anatomical abnormalities, and that I consent that the clinicians inform me of such findings.
* I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
* I wish/ do not wish (circle one option) to receive an electronic copy of my anatomical MRI scan.
* I wish/ do not wish (circle one option) to receive a summary of the findings, which can be emailed to me at this address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Future research:

* I agree to have my de-identified data used in future research related to the study.

Yes 🞏 No🞏

* I agree to have my de-identified data used in future research that may be unrelated to the current study. I understand that this research may be conducted overseas and may require that my de-identified data be sent outside of New Zealand/ Aotearoa.

Yes 🞏 No🞏

Participant’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: Date:             /               /

NHI (If known): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I agree to have my de-identified data to be used in future research

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Initial here)      |     Participant Number (Research use only):