Participant Information Sheet

Dr Joanne Lin
Research Fellow
The University of Auckland
Private Bag 92019, Auckland, New Zealand

Telephone: 64 9 373 7599 Ext 82255
Facsimile: 64 9 367 7192
Email: joanne.lin@auckland.ac.nz

Study title: Using brain imaging to measure brain inflammation

Locality: The University of Auckland
Ethics committee ref.: 19/NTB/8

Lead investigator: Dr Joanne Lin
Contact phone number: 3737599 ext. 82255

You are invited to take part in a study on test and validate electroencephalography (EEG) and magnetic resonance imaging (MRI) techniques to measure brain inflammation. 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 at any time.

This Participant Information Sheet will help you decide if you’d 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 family, whānau, friends, or healthcare providers. Feel free to do this.

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

This document is seven (7) pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

In this study, we are trying to test magnetic resonance imaging (MRI) scans to measure brain inflammation. Recent studies suggest that brain inflammation plays an important role in a number of neurological and psychiatric conditions. However, at this time, there are no methods that can reliably measure inflammatory processes in living humans.

Some EEG and MRI techniques have been suggested to be sensitive to brain inflammation; therefore, the goal of our research is to validate these techniques using a typhoid vaccine, which is a safe, experimental model of human brain inflammation in healthy individuals. This will involve administering a vaccine for typhoid to trigger a mild, short-lived immune response in the brain that we will measure with the EEG recording and MRI scan.
We are a group of scientists and clinicians based at the University of Auckland and who are studying brain inflammation. This study has been approved by a Health and Disability Ethics Committee. Contact details are given at the end of this sheet.

The study is funded by the Neurological Foundation of New Zealand, the Oakley Mental Health Research Foundation, the Maurice and Phyllis Paykel Trust, and the New Zealand Pharmacy Education and Research Foundation.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

You are reading this information sheet because you have seen advertisements and you have contacted us.

You may be eligible to participate if you are generally healthy and aged between 18 and 55 years of age. However, you will be excluded if you have typhoid vaccine within the past three years, received any other vaccine in the last month, have any inflammatory or autoimmune disorders, or are not able to have an MRI. We will ask you some other questions to ensure you are eligible and it is safe for you to take part.

This study will take up to 12 hours of your time and involve three (3) visits to our research centre. It is a crossover study, which means that you will get the vaccine injection during one session and the placebo injection during the other. We describe these visits below and have added a diagram at the bottom of this section to help you understand the timing of the visits and what happens at each visit.

- On the first day, you will come to our centre and we will confirm that you are eligible to take part in the study. This session will take approximately one (1) hour. We will ask you questions about your physical and mental health as well as medication and drug use history.
- If you are eligible and decide to take part, the second and third visits will be the main study sessions. Each session will take approximately five (5) hours, spaced at least a week apart. We will do a baseline EEG and MRI scan (more details about EEG and MRI are given below) and ask you to complete a questionnaire on your mood. A person trained to take blood samples will draw a sample from a vein in your arm (10 ml) that we will use to look at your immune system activity.
- After the baseline MRI, you will receive your study injection – either 0.5 ml of typhoid vaccine or placebo via an intramuscular (IM) injection in your deltoid (upper arm muscle). In this study, the placebo will be 0.5 ml IM injection of saline 0.9% solution. You will be randomly assigned to receive the vaccine or placebo injection in a predetermined order. However, the study team members you interact with will not know which group you are assigned to.
- Your heart rate, blood pressure, and body temperature will be checked every 30 minutes until the end of the session.
- You will be asked to complete the mood question every hour until the end of the session.
- Three (3) hours after your study injection, you will repeat the MRI scan, EEG, and give another blood sample (10 ml).
At the end of the study, you will be told the order which you received the study injections, so that you may plan for future vaccinations if necessary. After that, you will be free to go.

**WHAT DOES BRAIN IMAGING INVOLVE?**

For the MRI scans, you will change into clothes we provide for you. We will check that you have no metal on your body before you enter.

The MRI scanner is very loud and, for some people, can feel very enclosed. As such, it can be a little scary if you have not have in one before. We will give you headphones to protect your hearing. Let us know if you feel uncomfortable or apprehensive in any way. You will also give you an emergency buzzer that you can press so that you can leave the scanner at any time during the procedure. The MRI scan will take up to an hour. We will ask you to lie as still as possible during the scans.

![MRI scan](image)

An EEG recording involves putting on a soft cap that has 64 electrodes (black plugs in the picture to the left). The electrodes sit near your scalp and record electrical activity from your brain while you are resting.

The EEG take around 15 minutes to set up, and we will record for 10 minutes. You will be given instructions before you come to the second visit on how to prepare for the EEG.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

It is unlikely that you will obtain any personal benefit from taking part in the study; however, your participation will help us to progress the understanding of neuroinflammation and work towards better diagnosis/treatments.

Your MRI scan is for research and is not a diagnostic exam. The scans are not the same as those that a doctor might order. Research scans are not routinely reviewed; however, in the even that a condition that is assessed to be a clinical abnormality is detected through performing an MRI scan on you, you will be informed of this and will be advised to consult your general practitioner or other health professional of your choice. Because images are not routinely reviewed by a radiologist, we are unable to perform diagnostic scans for medical purposes. You should be aware that once you have been informed a clinical abnormality has been detected, this could affect your ability to obtain insurance, whether or not you take the matter further. EEG recordings are not able to detect clinical abnormalities. The recordings are for scientific purposes only and are not able to provide diagnostic information.
The typhoid vaccine is a licensed vaccine routinely given to people travelling to parts of the world where the likelihood of acquiring typhoid fever is high. As with all medicines, vaccines can have side effects. Sometimes they are serious, most of the time they are not. Serious problems from a typhoid vaccine are very rare. Side effects after a typhoid vaccine usually occur within the first 48 hours. The most common side effects include mild injection site reactions e.g. pain, redness, headache, weakness or fatigue, and mild muscle aches.

**WHO PAYS FOR THE STUDY?**

There will be no cost to you for taking part in this study. We will buy any food you need while you are taking part in the study. We recognize that each main study session will take around six (6) hours of your time and will provide you with $120 of vouchers in recognition of this inconvenience, a total of $240.

**WHAT IF SOMETHING GOES WRONG?**

If you were injured in this study, 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 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 ARE MY RIGHTS?**

Your participation in this study is entirely voluntary. It is up to you if you take part or not. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you do not want to take part, you do not have to give a reason. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

If you take part in the study, you have the right to access and/or correct any information about you collected during the study after your completion or withdrawal from the study. If we learn anything about your health status during the study that affects your health you will be informed of this. Any information you give us about yourself and all data collected from you will remain private and confidential. All MRI data will be stripped of identifiable information and stored as de-identified images on secure University of Auckland computers. Only members of the study team will have access to this information. Direct access may be granted to authorised representatives from the host institution and regulatory authorities to allow any study-related monitoring, audits, or inspections.

Your blood samples will only be identified by your allocated study number and handled by members of the study team. They will be stored in -80°C freezers within the School of Pharmacy until they are analysed; this may be one to two years after the completion of the study. After that, they will be destroyed by incineration.
WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

At the conclusion of the study, your personal data will be kept in locked cabinets in secure rooms at The University of Auckland and kept for 10 years. They will be shredded after this time. All electronic data files will be kept in a de-identified format so that there is no risk that you could be identified from these data. Your data will be identified by a unique trial-specific number in any database. Your name and other identifying information will not be included in any trial data electronic file.

Only members of the study team and appropriate regulatory bodies will be able to access your data, blood samples, and health information.

It can take quite a long time for us to analyse data from these kinds of studies. We hope to be able to tell you the final results one to two years after completion of the study. We plan to publish the result in specialised academic journals. If you want us to, we can send you a summary of the results in an easier format to read.

PARTICIPANTS OF MAORI DESCENT

If you are of Māori descent, you are encouraged to consult with your whanau, hapu or iwi regarding participation in this project. You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.

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

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Joanne Lin, Research Fellow  
Phone: 373 7599 x 82255  
Email: joanne.lin@auckland.ac.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:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: advocacy@hdc.org.nz

For Maori health support please contact:

He Kamaka Waiora (Maori Health Team)  
Telephone number: 09 486 8324 x 2324  
Email: hkw@adhb.govt.nz

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
Consent Form

Dr Joanne Lin
Research Fellow
The University of Auckland
Private Bag 92019, Auckland, New Zealand
Telephone: 64 9 373 7599 Ext 82255
Facsimile: 64 9 367 7192
Email: joanne.lin@auckland.ac.nz

Please tick to indicate you consent to the following

<table>
<thead>
<tr>
<th>Consent Statement</th>
<th>Yes ☐</th>
<th>No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been given sufficient time to consider whether or not to participate in this study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I consent to the research staff collecting and processing my information, including information about my health.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.</td>
<td>Yes ☐</td>
<td>No ☐</td>
</tr>
<tr>
<td>I agree to my blood samples being disposed of using established guidelines for discarding biohazard waste.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.</td>
<td>Yes ☐</td>
<td></td>
</tr>
</tbody>
</table>
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.  Yes □

I understand the compensation provisions in case of injury during the study.  Yes □

I know who to contact if I have any questions about the study in general.  Yes □

I understand my responsibilities as a study participant.  Yes □

I wish to receive a summary of the results from the study.  Yes □  No □

If yes provide contact details (email):

**Declaration by participant:**
I hereby consent to take part in this study.

Participant's name:

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**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:

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>