CENTRAL NORTHERN ADELAIDE HEALTH SERVICE
The Queen Elizabeth Hospital & Lyell McEwin Hospital

PARTICIPANT INFORMATION SHEET (HEALTHY CONTROLS)

A Magnetic Resonance Imaging (MRI) and Single-Photon-Emission Computed Tomography (SPECT) study of changes in the brain associated with changes in clinical parameters in Chronic Fatigue Syndrome (CFS).

Protocol Number:2009196

INVITATION TO PARTICIPATE

We invite you to participate in a research project which we believe is of potential importance.
However, before you decide whether or not you wish to participate, we need to be sure that you understand

why we are doing it, and
what it would involve if you agreed.

We are therefore providing you with the following information.
Please read it carefully and be sure to ask any questions you have.
The Doctor conducting the research will be happy to discuss it with you and answer any questions that you may have.
You are also free to discuss it with outsiders if you wish (family, friends and / or your local Doctor).
You do not have to make an immediate decision.
Your participation is purely voluntary.
Should you agree to enter the trial, you may change your mind and withdraw at any stage.

PARTICIPATION IS VOLUNTARY

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage without providing a reason.

Your decision to take part, not to take part or to withdraw will not affect your routine treatment, your relationship with those treating you, or your relationship with The Queen Elizabeth Hospital.

BACKGROUND TO THE STUDY

Chronic Fatigue Syndrome (CFS) is a relatively common serious disorder with an impact on people's quality of life equivalent to that of cancer, stroke or heart disease. Despite decades of research, the central cause of CFS is still not known. This is holding back the development of effective treatment.
Recently, we at TQEH have applied advanced new computer methods to assess CFS using magnetic resonance images (MRI) of the brain. This was the first time that our approach had been tried. In our preliminary study, we found extensive involvement of the brain in patterns that have not been reported before. Some of these results correlated with various measures of CFS sufferers' blood supply system. These results,

if confirmed, will greatly advance our understanding of CFS, which in turn will tell us which research should be done next to find effective treatment.
We now want to repeat this work for two reasons:

1. To make additions to our original method that should provide further insights into how the brain is causing CFS.
2. To confirm and improve upon our initial results. For such potentially ground-breaking observations to be accepted, we must show that they are reproducible with a new group of CFS sufferers and a new group of healthy controls. Also, by combining the old and new groups we will strengthen our results and may discover changes not evident using only one of the groups.

This research has attracted support from two private Australian charitable foundations: The Mason Foundation in Victoria and the JT Reid Foundation, also in Victoria. Their support is paying for scientists and a research nurse to conduct the research and is also paying for the MRI and SPECT scans.
We intend to compare 25 CFS sufferers and 25 otherwise matched healthy people in this new study.

PROCEDURES AND TREATMENT

The research involves collecting comprehensive medical information about you over a period of 6 days – your "study week". Mostly your contact will be our research nurse. During your study week you will

- have an interview with a research doctor and fill out questionnaires. We will combine the results of questions about your general health with our computer analysis of your brain scans to reveal how the brain is involved and compare this with the findings from the participants of this study who have CFS.
- keep a diary of your activities for 5 days. For each hour you just tick one of 5 activities. You can do this when you wake up and every few hours during the day.
- for the same 5 days wear about your ankle a device (an actimeter) to painlessly measure your physical activity levels.
- wear a blood pressure monitor for 24 hours. This small device will be delivered to your home and you will be shown how to wear it. Every half hour during the day and every hour during the night it automatically inflates a cuff around your arm and records your blood pressure. This is quite tight, but for a few seconds only.
- undergo tests with a psychologist to assess your cognitive function.
- have a Magnetic Resonance Imaging (MRI) scan at The Queen Elizabeth Hospital. You will spend about 20 minutes in the scanner.
- have a Nuclear Medicine brain (SPECT) scan. This involves an injection of a small amount of radioactivity (see below for risks). You will sit in the scanner for a few minutes at the time of injection, and 1 – 3 hours later you will lie in the scanner for about 20 minutes. We plan to do both the SPECT and MRI scans on a Saturday morning, although a weekday evening is also possible.
- Three trips are involved. Transport can be provided to and from the initial interview, the psychologist and the hospital. If you drive yourself, or are driven by family or friend, you will be reimbursed for expenses. These visits are expected to be on Monday morning, Wednesday morning and Saturday morning, the last two in the same week.

MEDICINES AND DRUGS

You will be given no medicines or drugs, and if you are already taking medications these do not need to be stopped.

DISCOMFORTS, RISKS AND SIDE EFFECTS

- A small injection for the Nuclear Medicine brain scan. This has no side effects.
- You will lie in an enclosed space in both the MRI scanner and the SPECT scanner. The MRI scanner is quite noisy.
- This research study involves exposure to a small amount of radiation from the Nuclear Medicine injection. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) per year. The effective dose from this study is about 5 mSv. The dose from this study is less than that from many diagnostic medical x-ray and nuclear medicine procedures. At this dose level no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be low and theoretically is approximately equivalent to 20% of the risk of being killed in a motor vehicle accident in Australia in 10 years.
- If you were to feel severe discomfort or pain, tell those performing the test and they will take immediate action to stop whatever is causing it.
- If you are worried about any effects that you experience, contact the research nurse or one of the researchers. You will be given their contact details.

PREGNANCY

Participants in this study must not be pregnant at the time of scanning, but no precautions need be taken to avoid becoming pregnant afterwards.

WHAT WILL HAPPEN TO THE INFORMATION COLLECTED?

- Your confidentiality will be protected by de-identifying the information you provide and your scans. You information will be identified by a number only.
- You will be given the results of the study when the data analysis has been completed.
- Your information will be stored for 15 years.

WHAT ARE MY RIGHTS?

If you become injured during this study, and your injury is a direct result of the effects of study procedures, The Queen Elizabeth Hospital will provide all reasonably indicated medical treatment. Your participation in this study shall not affect any other right to compensation you may have under common law.

- You can ask the Research Nurse or Study Coordinator for more information
- You will be provided with their contact details.

IS THERE ANY PAYMENT FOR PARTICIPATION?

- You will not be paid for your participation. Travel to and from the hospital will be provided, however. There will be no costs to you.

BENEFITS OF THE RESEARCH

- The proposed research may not be of benefit to you personally. However, our research findings may assist future patients with the same condition however.

WHAT IF I HAVE A QUESTION ABOUT THE STUDY?

- the contact details of the local researcher are

Research Nurse	*to be appointed*	
Research coordinators	Dr Richard Kwiatek	8267 1767
	Dr Leighton Barnden	8222 6438

The Central Northern Adelaide Health Service Ethics of Human Research Committee (TQEH & LMH) has approved this study.

Should you wish to speak to a person not directly involved in the study in relation to

- matters concerning policies,
- information about the conduct of the study
- your rights as a participant, or

should you wish to make a confidential complaint, you may contact The Executive Officer of this Committee, on (08) 8222 6841

CONSENT FORM

(HEALTHY CONTROLS)

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I, the undersigned .....

hereby consent to my involvement in the research project explained above.

- I have read the information sheet, and I understand the reasons for this study. The research worker has explained the ways in which it will affect me. My questions have been answered to my satisfaction. My consent is given voluntarily.
- I understand that the purpose of this research project is to improve the quality of medical care, but my involvement may not be of benefit to me.
- The details of the research project have been explained to me, including:
  - The expected time it will take
  - The nature of any procedures being performed, and the number of times they will be performed
  - Any discomfort which I may experience
- I have been given the opportunity to have a member of family or a friend present while the project was explained to me.
- My identity will be kept confidential, and nothing will be published which could possibly reveal my identity.
- My involvement in the study will not affect my relationship with my medical advisers. I understand that I am able to withdraw from the study at any stage without having to give a reason, and that by withdrawing it will not affect my treatment at this hospital in the future.

PATIENT SIGNATURE ..... **DATE** ……/……./…….

WITNESS: ..... **DATE** ……/……./…….

INVESTIGATOR ..... **DATE** ……/……./…….