SUBJECT INFORMATION SHEET

Chronic Fatigue Syndrome Patients

Study Title:	Comparison of Plasma Carnitine Levels in Patients with Chronic Fatigue Syndrome and Healthy Controls	
Study ID:	LC/06.4	
Researchers:	Stephanie Reuter (PhD Candidate) Phone: 8302 1872	Allan Evans (Supervisor) Phone: 8302 2310
Institution:	Sansom Institute University of South Australia Frome Road Adelaide, SA, 5000	

STUDY INVITE

You are invited to participate in a clinical research study investigating the blood levels of a naturally occurring compound called carnitine in Chronic Fatigue Syndrome patients and healthy subjects. Carnitine is found in all mammals and is involved in energy production. Previous research has suggested that the levels of carnitine in the blood of patients with Chronic Fatigue Syndrome are different to those in healthy people.

The purpose of this study is to investigate if the levels of carnitine are different in Chronic Fatigue Syndrome patients compared to healthy subjects.

This study is being conducted by researchers from the Sansom Institute, University of South Australia as part of a PhD project.

Participation in this study is entirely voluntary.

This project has been approved by the University of South Australia's Human Research Ethics Committee.

WHAT IS INVOLVED?

A blood sample will be collected on a single occasion. This blood sample will then be used to determine the amount of carnitine and its related compounds in plasma (a component of blood). The amount of carnitines will be compared to results obtained from healthy subjects.

Basic demographic details and details about your Chronic Fatigue Syndrome will also be recorded.

WHO CAN PARTICIPATE?

People, over 18 years of age, who have been diagnosed by a doctor as having Chronic Fatigue Syndrome can participate.

For safety reasons, patients who are HIV, Hepatitis B or Hepatitis C positive are excluded from participating. In addition, patients who have taken any medication that contains carnitine (such as some multivitamins) within the last 2 months are excluded.

WHAT DO I DO IF I WOULD LIKE TO PARTICIPATE?

If you would like to participate in this study you are asked to contact Stephanie Reuter via email (stephanie.reuter@unisa.edu.au) or on 8302 1872. The study procedures will be explained and you will be asked to sign a consent form indicating your willingness to participate in the study. You will then be asked to complete a

short questionnaire which will include details about you and your condition. A blood sample will then be collected at a convenient location for you, by a person who is trained in blood collection.

You may withdraw from the study at any time, and this will have no impact on your medical care.

WHAT IF I DON'T WANT TO PARTICIPATE?

The decision to participate in this study is entirely yours. A decision not to participate will have no impact on you or your medical care.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF PARTICIPATING?

This study is part of a research effort to develop additional information about the blood levels of carnitine in Chronic Fatigue Syndrome patients and may provide benefit to others in the future. You should understand that you will not receive medical benefit from this study.

The collection of blood samples is associated with a slight risk of bruising and infection. Your blood sample will be collected by a trained person using sterile techniques.

Study participants will be offered a $20 voucher as a token of appreciation for their time and any inconvenience involved.

WHAT HAPPENS TO THE INFORMATION COLLECTED ABOUT ME?

All information collected during the study will be confidential. Data will be retained by the Sansom Institute, University of South Australia in a locked facility for a period of 7 years, after which time it will be destroyed in a confidential manner providing data analysis and reporting of results is complete. Study data will only be accessible to researchers involved in the study.

All records containing personal information will remain confidential and no information which could lead to identification of any individual will be released.

The researchers will take every care to remove responses from any identifying material as early as possible. Likewise, individual's responses will be kept confidential by the researchers and not be identified in the reporting of the research. However, the researchers cannot guarantee the confidentiality or anonymity of material transferred by email or the internet.

WILL I RECEIVE A COPY OF THE RESULTS OF THE STUDY?

In the event that the results of this study are published in a scientific journal, participants may request to be provided with a copy of the publication.

NEED MORE INFORMATION?

If you have any questions about the rights of participants or if you have any ethical concerns about the project, you should contact:

VICKI ALLEN, EXECUTIVE OFFICER
Human Research Ethics Committee
University of South Australia
Phone: [08] 8302 3118

If you have any questions about the study, you should contact:

STEPHANIE REUTER
Sansom Institute
University of South Australia
Email: stephanie.reuter@unisa.edu.au
Phone: [08] 8302 1872