IRB Approved: 09/21/2017
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CORIHS, Stony Brook University

Stony Brook University

# RESEARCH CONSENT FORM

**Project Title:** Sex differences in exercise-related post-exertional malaise in ME/CFS

**Principal Investigator:** Fred Friedberg, Ph.D.

**Department:** Psychiatry

You are being asked to be a volunteer in a research study. You are encouraged to take your time in making your decision. You may want to discuss this study with your friends and family.

## Purpose

The purpose of this study is to examine heart rate and blood pressure, physical activity levels, and symptoms that may be linked to post-exertional malaise (PEM) in people with chronic fatigue syndrome (CFS). PEM occurs when routine activities trigger symptom flare-ups that may last from several hours to several days or more.

For all individuals in the study, we will measure: PEM and performance on two six minute walking tests on two consecutive days. We will also measure heart rate and blood pressure with monitoring devices, activity levels with a waist-worn activity monitor and symptom levels with an online diary. Forty subjects will participate in this study. You are eligible for this study because you have been tentatively diagnosed with chronic fatigue syndrome with post-exertional malaise.

## Procedures

**If you decide to be in this study,** you will be asked to do the following: complete several questionnaires about your symptoms and functioning (10-20 min.). You will also be mailed the heart monitor and the activity monitor with instructions on how to use them and how to fill out the home-based web diary. Then for the 15 days of the study, we will ask you to wear the activity monitor during your waking hours, to wear a heart monitor for 10 min a day in the evenings, and to complete a 10 minute online daily diary of your symptoms. During your first and second visits to the Health Sciences Center and be asked to do two six minute walk tests, with knee squats before each walk, over two consecutive days. You will wear a heart monitor and blood pressure monitor during the tests. This six minute walk test measures how far you walk in six minutes when walking as fast as you can. During this test you may slow down or stop at any time in the event of chest pain, shortness of breath, fatigue, pain or any other discomfort. Thirty-seconds of knee squats will precede each walk test. During the squats, you may experience lightheadedness or faint feelings. After the second walk test, you will continue with your home monitoring for another week and then mail back the heart and activity monitors in pre-paid mailers.

**Risks/Discomforts**

**The following risks/discomforts may occur as a result of your participation in this study:**

You may experience some tiredness and annoyance from completing the questionnaires and the diaries and from wearing the activity monitor and the heart rate monitor. Also you may feel some mild discomfort when removing the heart rate sensors from your skin. This sensation is similar to removal of a band- aid. Although unlikely, the electrodes used to attach the heart monitor to the skin may leave temporary red marks. The six minute walk test is likely to produce a symptom flare-up during and after the test. The symptom flare usually resolves to pre-test levels within 48-72 hours. The knee squats may produce lightheadedness or faint feelings. Usually sitting down will resolve these symptoms. Also you will be advised to eat salty snacks and fluids prior to the knee squats exercise (e.g., Gatorade) which may help prevent the lightheadedness if it occurs.

**Benefits**

**The following benefits to you are possible as a result of being in this study:**

There is no health benefit to you, but your participation will advance the understanding of chronic fatigue syndrome.

**Payment to You**

The total compensation to be paid for each participant will be up to $100. You will be paid in installments as you complete each aspect of the study (baseline, exercise tests, follow-up). You will be paid $50 for completion of the one-week baseline assessment (two six minute walking tests, questionnaires, activity and heart monitors). For the one-week follow-up, you will be paid an additional $50 for completion of the activity and heart monitors. You will not be paid if you drop out before completing the first walk test.

**PAYMENT TO THE INSTITUTION**

This project is funded by a grant or contract from the National Institutes of Health (NIH) to the Research Foundation of Stony Brook University, in support of the Investigators' work on this study. Amount of payment from this sponsor has been set by NIH.

**Confidentiality**

We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get

from you in this study with the study team, Stony Brook University's Committee on Research Involving Human Subjects, and applicable Institutional officials. However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

While you are in this study we have requested that you provide a note from your doctor regarding your diagnosis. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, and applicable institutional officials, and the National Institutes of Health) as well as: your private doctor.

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Dr. Fred Friedberg. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter.
When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

If you are paid $600 or more a year as a research subject, your social security number will be reported to those in charge of taxes. You may have to pay taxes on this money.

**Costs to You**

There are no costs to you for participating in this study.

**Alternatives**

Your alternative to being in this study is to simply not participate.

**In Case of Injury**

If you are injured as a result of being in this study, please contact Dr. Fred Friedberg at telephone # 631 638-1931. The services of SUNY-Stony Brook's

University Hospital will be open to you in case of such injury. However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospitalization.

## YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep.
- You do not lose any of your legal rights by signing this consent form.

## QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. Fred Friedberg, Principal Investigator, at telephone # (631-638-1931).

- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Judy Matuk, Committee on Research Involving Human Subjects, (631) 632-9036, OR by e-mail, judy.matuk@stonybrook.edu.

- Visit Stony Brook University's Community Outreach page, http://www.stonybrook.edu/research/orc/community.shtml for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

| Subject Name (Printed) | Subject Signature | Date |
|---|---|---|

| Name of Person Obtaining Consent | Signature of Person Obtaining Consent | Date |
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