

Georgia State University
Department of Biology
Informed Consent

Title: Mechanisms of Mitochondrial Defects in Gulf War Syndrome
Principal Investigator: John M. Shoffner, M.D.
Sponsor: Department of Defense, Grant # GW080138

I. Purpose:

You are invited to voluntarily participate in a research study funded by the Department of Defense (DOD). The purpose of the study is to investigate possible causes for Gulf War Syndrome. Gulf War syndrome is associated with increased incidences of amyotrophic lateral sclerosis (Lou Gehrig's Disease), pain syndromes, muscle complaints that include fatigue and myalgias (muscle pain), as well as other neurological symptoms. Abnormalities in the part of the cell known as mitochondria have been delineated in Gulf War Syndrome. Mitochondria are the "power plants" of the body. Mitochondria take the food you eat and break the food down into a form of energy that the body can use. We propose that Gulf War Syndrome is determined by a complex interaction of factors that interfere with mitochondrial function. This study will be the first investigation of mitochondrial function in Gulf War Syndrome. Our objective is to establish the cause for symptoms in affected veterans, develop testing that can more easily identify Gulf War Syndrome, and ultimately develop treatment protocols for Gulf War Syndrome.

You are invited to participate because you are diagnosed with Gulf War Syndrome. A total of 50 participants will be recruited for this study. Participation will require 1.5 – 2 hours of your time at a single clinical visit with Dr. Shoffner.

II. Procedures:

If you decide to participate, the following procedures will be performed.

Clinical Evaluation: Dr. Shoffner will ask for you to supply your medical records which include clinical notes, laboratory records, pathology reports, and radiology records. Obtaining the records and sending them to Dr. Shoffner will be your responsibility. Dr. Shoffner will review the records and meet with you for clinical discussion and examination. During this visit, Dr. Shoffner will explain the research study and answer any questions that you have.

Blood Draw (Collection): If you agree to participate in this study, no more than 45 ml (3 tablespoons) of blood will be drawn from your forearm (the vein at your elbow typically used to draw blood) only one time. **Common measurements: 5 ml=1 teaspoon; 15 ml=1 tablespoon**

How the blood will be used: Research testing designed to assess how the blood cells use energy will be done on the blood that is collected. The blood cells will be culture. Culturing cells means that the blood cells are fed with nutrients in the lab. The cells will grow in a container that allows us to have a large supply of blood cells that can be used for research. Blood samples will be stored at the expense of Medical Neurogenetics, LLC. The samples will be assigned a number by Dr. Shoffner. Your name will not appear on the sample. Only Dr. Shoffner will be able to link your name to the samples.

The tests performed as part of this study are not to be used as a substitute for your normal medical care. You should know that this study is not designed to detect any disease or abnormal condition. If you wonder whether you may have a disease or abnormal condition, please consult your doctor. Participating in this research study will not help you to know whether you have a disease or abnormal condition.



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Skin Biopsy: A tiny skin sample will be obtained from your arm which is approximately the size of the top of a thumbtack (a small circle no more than ¼ inch across). Dr. Shoffner will show you the size of the piece of skin removed during the clinical appointment. The skin sample will be cultured. Culturing skin cells means that the skin cells are fed with nutrients in the lab to grow a certain type of cell called fibroblast cells which allows us to have a large supply of cells that can be used for research. Skin cells will be stored at the expense of Medical Neurogenetics, LLC. The samples will be assigned a number by Dr. Shoffner. Your name will not appear on the sample. Only Dr. Shoffner will be able to link your name to the samples.

The procedure for obtaining the skin cells (skin biopsy) is given below. Skin biopsy is a simple and routine office procedure. The skin biopsy will be performed by Dr. Shoffner.

1. An area of skin on your arm will be numbed by an injection of lidocaine (a numbing medicine) so that you do not feel any pain. The skin becomes numb in less than 5 minutes.
 - a. Lidocaine is the most commonly used medication to numb the skin for a skin biopsy. An allergic reaction to lidocaine is extremely rare. By signing the consent form you affirm that Dr. Shoffner has asked you whether you are aware of having experienced an allergic reaction to lidocaine at any time in your life. By signing the consent form you also affirm that your response to this inquiry was “NO KNOWN ALLERGIC REACTION TO LIDOCAINE”. If an allergic reaction to lidocaine (the numbing medicine) did occur during the procedure, Dr. Shoffner would assess the reaction and manage your reaction according to standard medical approaches. If an allergic reaction did occur, the study does not make any provisions for medical care or for the payment of any medical services associated with the reaction.
2. The skin will be cleaned with alcohol and the skin sample will be obtained using a standard punch biopsy blade and sterile scissors.
3. The procedure takes approximately 10 minutes.
4. An antibiotic (Bacitracin ointment) will be applied to the biopsy site.
5. The biopsy site should have a clean application of Bacitracin ointment and a clean bandage applied daily for 3 days. We will give you these supplies after the skin biopsy is complete.

III. **Risks:**

Blood Draw Risk: The possible risks and/or discomforts associated with the skin biopsy are minimal. The risks associated with blood drawing include discomfort from insertion of the needle (common), fainting at or about the time of blood drawing (infrequent), bruising at the site of blood drawing (infrequent), and infection at the same site (rare). Any complications observed at the time of blood drawing will be assessed by Dr. Shoffner and treated in a fashion consistent with standard medical care.

Skin Biopsy Risk: The possible risks and/or discomforts associated with the skin biopsy are minimal. The risks are as follows.

1. **Minimal risk for collection of the skin sample:** There is some possibility of bruising, swelling, bleeding, and infection at the site of the skin biopsy. In rare instances, a person may faint during the biopsy. For your safety and comfort, you will be reclining on an examination table. Please inform Dr. Shoffner and your local physician if you experience pain or bleeding from the site of the skin biopsy once you leave Medical Neurogenetics, LLC. No stitches are required.



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2. **Scarring:** The resulting scar from the skin biopsy is tiny and is typically barely visible. Occasionally, an individual has abnormal scarring. This abnormal scarring is often referred to as “keloids”. This means that the scar is bigger and more visible than usual. By signing the consent form you affirm that Dr. Shoffner has asked you whether you are aware of having abnormal scarring. By signing the consent form you also affirm that your response to this inquiry was “NO KNOWN ABNORMAL SCARRING WITH MINOR INJURIES OR SURGERY”. If abnormal scarring did occur, the study does not make any provisions for medical care or for the payment of any medical services associated with the scarring.
3. **Lidocaine (numbing medicine) injection:** There may be some discomfort associated with the lidocaine injection which is a mild burning sensation lasting only a few seconds.

If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator for this study, (John M. Shoffner, MD Phone number 678-225-0222). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221.

IV. Benefits:

Participation in this study may not benefit you personally. We hope to gain information about the cause of Gulf War Syndrome. This may eventually lead to new forms of diagnosis and treatment in the future.

V. Voluntary Participation and Withdrawal:

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. If you sign this consent form you are allowing us to use your personal health information for this study and for future studies performed by Dr. Shoffner. You will not lose any healthcare benefits to which you are otherwise entitled.

Tissue specimen retention and use are discussed in Section IX.

Withdrawal of permission to use medical records. You have the right to say that you do not want us to use your personal health information (medical records) after we have collected it. If you decide you don't want us to use your information anymore, you must write a letter asking us not to use your information. If you don't want us to use your information anymore, we will stop using it, but any information that we have already used in the study will not be removed. You may not be able to look at or get a copy of your health information that you gave us while we are doing the research; however you will be able to look at or get a copy of your healthcare information at the end of the study. If you decide to withdraw permission to use your medical records for this study or for future studies, you must send a letter to Dr. Shoffner at the address below.

Dr. John Shoffner

Medical Neurogenetics, LLC

One Dunwoody Park South, Suite 250, Atlanta, Georgia 30338



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VI. Confidentiality:

We will keep your records private to the extent allowed by law. Dr. John Shoffner and representatives of the U.S. Army Medical Research and Material Command will have access to the information you provide and to the study records. Medical information will be scanned to our computer and will be stored electronically on a password protected computer. Paper copies of the medical records received will be destroyed. Dr. Shoffner will keep the password for access to the computerized medical records. Your name and other facts that might point to you will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.

The health information you give us will be used in this research study. We will use the personal health information that you have given us which includes clinical notes written by your doctors, laboratory records, and radiology records. Dr. Shoffner and representative of the U.S. Army Medical Research and Material Command will be able to look at your personal health information. Dr. Shoffner will review the clinical records so he can work on this research study.

VII. Contact Persons:

Call Dr. John M. Shoffner at 678-225-0222 if you have questions about this study. If you have questions or concerns about your rights as a participant in this research study, you may contact Susan Vogtner in the Office of Research Integrity at 404-413-3513 or svogtner1@gsu.edu.

VIII. Copy of Consent Form to Subject:

We will give you a copy of this consent form to keep.

IX. Sample Donation to Medical Neurogenetics, LLC and to Georgia State University

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Georgia State University and Medical Neurogenetics, LLC. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

Samples will be stored at the expense of Medical Neurogenetics, LLC. The samples will be assigned a number by Dr. Shoffner. Your name will not appear on the sample. Only Dr. Shoffner will be able to link your name to the samples.

If samples are shared with other investigators, the samples will only have a number on them. The number will NOT be able to be linked to your identity or to your medical records. Only Dr. Shoffner will be able to link the number assigned to your sample to your identity and to your medical records.

X. Georgia State University Disclaimer:

If you have any question about this study, or believe you have suffered any injury because of participation in the study, you may contact Dr. John Shoffner at 678-225-0222. No arrangements have been made to provide subjects with treatment or reimbursement for treatment should an injury occur. Georgia State University and Medical Neurogenetics, LLC have not set aside funds to pay for this care associated with injury



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during this study or to compensate you if something should occur.

If you are willing to volunteer for this research, please sign below.

Participant

Date

Principal Investigator or Researcher Obtaining Consent

Date

