

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient
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INSTITUTE: National Institute of Neurological Disorders and Stroke

STUDY NUMBER: 16-N-0058 PRINCIPAL INVESTIGATOR: Avindra Nath, MD

STUDY TITLE: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

Initial Review Approved by the IRB on 12/16/15

Amendment Approved by the IRB on 07/27/16 (C)

Date Posted to Web: 09/29/16

ME/CFS (Focus Group)

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Purpose of This Study

The purpose of this study is to learn more about myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) that starts after an infection.

Background

Chronic fatigue syndrome (CFS) and myalgic encephalomyelitis (ME), also called systemic exertion intolerance disease (SEID) by the Institute of Medicine, are terms used to describe extreme fatigue and post-exertional malaise along with other symptoms like pain, sleep problems, depression and anxiety. "Post-exertional malaise" is a feeling of profound exhaustion after exercise. The cause of ME/CFS is not known. At times, this condition is triggered by an infection. The purpose of this study is to learn more about ME/CFS that starts after an infection. To study ME/CFS, participants will have physical and psychological examinations about their symptoms and ME/CFS effects on many aspects of their

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (07-09)

P.A.: 09-25-0099

File in Section 4: Protocol Consent (2)

STUDY NUMBER: 16-N-0058

CONTINUATION: page 2 of 5 pages

lives. There will be tests of blood and various body fluids and magnetic resonance imaging. Some participants will have exercise stress testing.

We need to develop a new way to assess how people experience post-exertional malaise. We will be developing a structured interview. We will test what questions work best during an interview about post-exertional malaise by holding focus groups. The focus group will include people with ME/CFS who are interviewed by telephone conference. We will ask sample questions and ask focus group members to discuss the questions, their answers and their ME/CFS experience with each other. We will record the telephone call. We will use the information obtained from the focus group to identify the best questions to ask about post-exertional malaise.

With this consent form, we describe the study for those participating in a focus group. Those in the focus group will not participate in other parts of the study, including visits to NIH and research examinations.

The study is run by the National Institute of Neurological Disorders and Stroke (NINDS), within the NIH.

Study Population

Up to 186 people will participate in this study. There will be 4 groups of participants.

- PI-ME/CFS group -People with ME/CFS whose fatigue started after an infection
- Lyme group- People who had Lyme disease, were treated, and don't have symptoms anymore
- Healthy Volunteer group- those in good general health
- Focus Group- Those with ME/CFS participating in a phone conference only

Who Can Be In This Study

You may be eligible to participate in a focus group if you are:

- 1) 18 years old or older
- 2) Have been told by your doctor that you have ME/CFS
- 3) Have had post-exertional malaise
- 4) Able to speak, read, and understand English
- 5) Are able to give informed consent for yourself

Who May Not Be In This Study

You may not be eligible to participate in a focus group if you:

- 1) Are not willing to be audiotaped during the focus group telephone call
- 2) Want to participate in the other parts of the NIH ME/CFS research study
- 3) Are an employee of the National Institutes of Health

Procedures

Obtaining consent:

To see if you are able to participate in a focus group, we will talk to you on the phone. We will ask about your diagnosis and experience with ME/CFS. If you qualify for the focus group, we will send you this informed consent form. If you are interested in participating, we will set up a time to call you to discuss the study and informed consent form. Please have another adult with you on the phone call. We will answer any questions you have. If you agree to participate, please sign and date this consent form and have your witness sign and date this consent form. Then mail the signed consent form back to us in the self-addressed stamped envelope we will provide. Once we get your signed informed consent form, we will call you with the date and time for the focus group telephone call.

STUDY NUMBER: 16-N-0058

CONTINUATION: page 3 of 5 pages

Focus Group Telephone Conference.

The focus group telephone conference will be a joint discussion with four to nine other participants with ME/CFS. Study staff will lead the focus group call. Each member of the focus group will be asked about his or her post-exertional malaise. Participants will talk to study staff and each other about their experiences. The telephone call will last one to two hours. The telephone discussion will be recorded.

To keep the identity of focus group participants private, we will only use first names during the teleconference. You can use any name you want; you do not have to use your actual first name if you do not want to.

Your participation in this study is finished at the end of the teleconference.

Risks, Inconveniences and Discomforts

The main risk of being in a focus group for this study is a loss of privacy or confidentiality. Others on the phone call may be able to figure out who you are. You may feel uncomfortable talking about your ME/CFS experiences in a group. Please remember that you do not have to share any information that makes you uncomfortable.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of

- We will report certain contagious diseases, information about child or elder abuse or neglect and threats to yourself or others.
- Information needed for your care during a medical emergency may be given to those who are treating you.

Potential Benefits

There is no direct benefit to you from participating in this research study. However, we hope to learn more about post-exertional malaise.

Right of Withdrawal and Conditions for Early Withdrawal

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. We can remove you from the study at any time if we believe that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 16-N-0058

CONTINUATION: page 4 of 5 pages

Discussion of New Findings with You

We will share with you any new information that may affect your willingness to participate. The information we obtain from this study will not provide information on your health.

Alternatives to Participation or Treatment

The alternative to participating in this study is to not participate.

Compensation and Travel costs

You will not be compensated for your participation.

PATIENT IDENTIFICATION**CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

STUDY NUMBER: 16-N-0058

CONTINUATION: page 5 of 5 pages

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Avindra Nath, Building 10/7C-103, 301-496-1561, or the Lead Associate Investigator, Dr. Brian Walitt, Building 10/3B-19, 301-509-6825.

You may also call the Clinical Center Patient Representative at (301) 496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:			
<p>A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.</p> <p>_____ Signature of Adult Patient/Legal Representative Date</p> <p>_____ Print Name</p>	<p>B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)</p> <p>_____ Signature of Parent(s)/Guardian Date</p> <p>_____ Print Name</p>		
<p>C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.</p> <p>_____ Signature of Parent(s)/Guardian Date _____ Print Name</p>			
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM DECEMBER 16, 2015 THROUGH DECEMBER 15, 2016.			
<p>_____ Signature of Investigator Date</p> <p>_____ Print Name</p>	<p>_____ Signature of Witness Date</p> <p>_____ Print Name</p>		