

INSTITUTE: National Institute of Environmental Health Sciences

STUDY NUMBER: 11-E-0072 PRINCIPAL INVESTIGATOR: Frederick Miller, M.D., Ph.D.

STUDY TITLE: Environmental Risk Factors for the Anti-Synthetase Syndrome

Initial Review Approved by the IRB on 09/28/10

Amendment Approved by the IRB on 02/04/11 (A)

Date Posted to Web: 02/10/11

Healthy Minor Assent

Assent for Healthy Minor Subjects

Your parents have brought you to your doctor's office or to the National Institutes of Health (NIH) because you are healthy. This study is comparing healthy people like you to other people who have a disease called myositis, which causes them to be weak. We are trying to understand more about why some people became sick with myositis. This study may not help you directly, but by participating in the study people with myositis may be helped.

What We Are Asking You to Do

Your doctor or study doctor and possibly other doctors and nurses will ask you questions and examine you. We would like to take a blood sample from your arm. It will hurt a little when we take the blood out, but if you want, we can use a numbing medicine on your skin so that it will hurt less when blood is drawn out from your arm. Sometimes there will be a bruise afterwards.

You may also be asked to have some or all of the following tests or questions below to see how parts of your body function. You may be asked to come back another time to have more blood drawn if it cannot be drawn safely the first time, but you do not have to come back if you do not want to. These blood tests may help your doctors confirm that you are not sick.

- 1) Doctors in this study will get copies of your medical records from your regular doctor but they will not share this information unless your parents ask us to.
- 2) Your mother or father will spend about 1 - 2 hours filling out forms about your medical history and the types of things you have come in contact with at home and elsewhere. Your parents will also be asked if you have had certain infections, have been doing heavy exercise or physical exertion, reacted to the sun in a particular way, used tobacco or alcohol, or had difficult or stressful events in your life.
- 3) Your doctor or a doctor at NIH will ask you questions and examine you. If new problems are found that your doctor did not know about, more tests may be done or recommended in order to take better care of you.
- 4) Depending on your age and weight, you will have up to 6 tablespoons (90 ml) of blood taken for tests. The amount of blood drawn will be a safe amount.

The tests that will be done on your blood include studies to find out how your blood cells work and if they work differently from other people with myositis. These tests will also see if you have proteins in your blood that can make

STUDY NUMBER: 11-E-0072

CONTINUATION: page 2 of 3 pages

you sick. Some blood samples will be used for isolating and studying DNA (your genes). We will compare the spellings in your genes and from other people with myositis to the genes from people without myositis to find any differences. We plan to study many different parts of your DNA. Information about your genes and the genes of other myositis patients enrolled in this study will be placed together into an Internet database that does not identify you personally. But, your specific genetic information may be available to scientists who have approval to look at the DNA results and ask specific research questions. We will also look to see if you have had certain infections.

One of the blood tests you may have is for the AIDS virus. If this test shows that you have infection with the AIDS virus, we will tell you right away and make sure that you know how to prevent AIDS from spreading from you to anyone else. We will also tell your parents of the results of this test. If you have the AIDS virus infection we will refer you to a doctor who is an AIDS expert. Some of your blood will be frozen, with a code number but not your name on the label. The frozen sample may be sent to other researchers in the future for other studies. We will give important results of your studies to your doctors if it is important for them to know this information to take better care of you.

QUESTIONNAIRES AND FOLLOW-UP CONTACTS

In order to determine if you have been exposed to certain things at home and elsewhere, we will ask your parents to report about your past jobs, hobbies, other activities, infections, stressful life events, and other exposures by having your parent's complete questionnaires. Depending on the answers to these questions, your parents may be contacted by phone by persons involved in this study to clarify certain answers or if additional samples or information are needed in the future.

You or your doctor may be contacted in the future for additional information or to give additional blood samples, and you may be asked to consider participating in future studies. Your participation in this and all future studies is completely up to you. You may withdraw from this study at any time, and you may decline to participate in any follow-up studies, without in any way affecting your eligibility for participation in future research at the NIH.

When you become 18 years of age, you may re-contact us to sign an adult consent form or even choose instead to withdraw your samples and data from the study and stop doing the study. You are not required to sign an adult consent form when you become 18 years old to remain enrolled in the study.

PAYMENT

You will be paid \$100 for being in this study after you have finished all the parts of the study. In some cases, you may be asked to return to repeat some of the research tests and, if this occurs, you and your doctor will again be paid \$100. If you enroll from home with your local doctor, your doctor will also be paid \$100 for his/her time.

What You Have To Decide About

We want you to understand what we do and why we do it. Please ask us to explain whatever you don't understand.

Please write your name on this paper if you say yes to what we have explained here. This shows that you agree to have a doctor exam you, to have blood drawn and answer questions about how you feel and about other parts of your history. You have also agreed to have other tests done if they will help your doctors find out more about your illness. You can change your mind later if you say yes now. Just tell us if you don't want to take part any longer.

STUDY NUMBER: 11-E-0072

CONTINUATION: page 3 of 3 pages

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions.
I agree to take part in this study.

Signature of Minor Patient: _____ Date: _____

Print Name: _____

Signature of Investigator: _____ Date: _____

Print Name: _____