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<b>MEDICAL RECORD</b>	<b>MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
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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: 02/17/11

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Myositis Assent

### **Assent for Children with Myositis**

Your parents have brought you to your doctor's office or to the National Institutes of Health because you have a disease called myositis, which causes your muscles to be weak and may be causing you other problems. This study is comparing people like you who have myositis to healthy people who don't have a disease. We are trying to understand why some people became sick with myositis. This study may not help you directly, but by being in the study, other people with similar problems may be helped. The results from this study may give your doctor information that may help him/her plan the best treatment for you.

### **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 tests may help your doctors see how sick you are or to confirm that you are not sick. They may help your doctors choose the best treatment for you.

- 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 before you were diagnosed with myositis.
- 3) Your doctor or a doctor at NIH will ask you questions and examine you to see how myositis has affected 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.

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**PATIENT IDENTIFICATION**

**MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

NIH-2514-2 (10-09)

P.A.: 09-25-0099

File in Section 4: Protocol Consent (4)

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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 or from healthy people. These tests will also see if you have proteins in your blood that can make you sick. Some blood samples will be used for isolating and studying DNA, which is the inherited material from your parents that makes up your genes and determines what proteins are made in your body. We will compare the spellings in your genes and those from other people with myositis to the genes from people without myositis to find out if there are 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, and 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.

**Because you have myositis you may have the additional tests below if your doctor thinks this will help him/her take better care of you:**

Electrocardiogram: This is a test measuring the electrical activity of your heart. Wires are attached to your chest, arms and legs using a sticky paste which takes only a few minutes. There is no pain from this test. An echocardiogram or sound-wave study of your heart function may also be done.

Pulmonary Function Tests: These tests tell us how your lungs work if you are having problems breathing. You would have to blow into a tube for a few seconds. You have to be at least 7 years old to do this test.

Chest X-ray: If you are having problems with your breathing, an x-ray picture of your chest may be made to check your lungs.

Chest CT scan: If your breathing needs to be checked on further, you may have a chest CT scan. The test involves having you lie on a padded table, which is slowly moved into a large tube inside the machine where X-ray pictures of your chest will be taken. This will not hurt, but you will have to lie very still in a machine with a small space for about 15 minutes. If you feel anxious about this, let us know and we will not do this test. You will be able to talk with the person doing this test any time and stop it if you want.

In order to have X-ray tests, teenage girls will have a test to tell if they are pregnant. If this test shows that you are pregnant, we will tell you right away. We will also tell your parents of the results of this test after we tell you. If you do not want us to tell your parents the result of your pregnancy test, please tell the doctor right now. If you are pregnant, you will not be able to have the chest X-ray or the chest CT scan in this study.

Magnetic Resonance Imaging Scan of the Legs: This study produces a picture of your leg muscles using magnetism. The test involves having you lie on a padded table, which is slowly moved into a large tube inside the machine. You will have to lie very still for the test, approximately 30 minutes. This will not hurt, but you will have to lie very still in a machine with a small space. If you feel anxious about this, let us know and we will not do this research test. You will be able to talk with the person doing this test any time and stop it if you want.

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Other tests may be recommended to help your doctors plan the best treatment for you. For all of the tests, the doctors will talk with you and your parent or guardian about them and ask your permission before we do them. If you or your parent or guardian does not want to do any of these tests, we will not do them.

You may benefit from being in this study. We will tell you, your parents and your doctors the results of our studies so they can take better care of you. You will **not** receive treatment for your myositis at NIH in this study. The doctors you meet at NIH (if you enroll at the NIH) will **not** become your regular doctors. We will, however, work with your doctor and suggest treatments to that doctor.

### **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 or 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 examine 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.

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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: \_\_\_\_\_