
MEDICAL RECORD	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • 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: 03-E-0099 PRINCIPAL INVESTIGATOR: Frederick Miller, M.D., Ph.D.

STUDY TITLE: Pathogenic Studies in Families with Twins or Siblings Discordant for Systemic Rheumatic Disorders

Continuing Review Approved by the IRB on 11/29/10

Amendment Approved by the IRB on 11/29/10 (N)

Date Posted to the Web: 1/25/11

Minor Twin Sibling Assent

Your parents have brought you to your doctor's office or the National Institutes of Health (NIH) because you or your brother or sister have a rheumatic disease, which can cause your joints or muscles to hurt or can cause you other problems. To understand what may cause rheumatic diseases, which are called rheumatoid arthritis, lupus, scleroderma and myositis, we will be studying families in which two siblings of the same gender (that means either two brothers or two sisters) are within four years of age and one has developed a systemic rheumatic disease and one has not. This study may provide information to your or your brother's or sister's doctor, which may help him/her know the type of disease you might have or confirm that you don't have any disease at all. You may also help us learn how to take better care of you or other children with these diseases.

What We Are Asking You To Do

Your doctor and possibly other people who take care of sick people in the hospital will ask you questions and examine you. We would like you to give us a sample of your urine and also 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. We will also be asking your mother and father to give us blood and urine samples for this study.

You may also be asked to undergo some or all of the following tests or questions below to see how other 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 and urine tests may be helpful to your doctors to see how sick you are or to confirm that you are not sick.

1) Researchers at the NIH will obtain your records from your regular doctor but we will not share this information unless your parents ask us to.

2) Your mother or father will spend about 2 - 3 hours completing forms about your medical history and the types of exposures you had at home and elsewhere. Your parents will also be asked if you had had certain infections, received vaccinations, were taking any pills, had jobs or a lot of sun exposure, or had difficult events in your life during the year before the diagnosis of your disease. If you are well, they will be asked the same questions covering the year before the diagnosis of your brother's or sister's disease.

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 (12)

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: 03-E-0099

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3) If you are 16 - 17 years old, you will spend about an hour or two answering questions about your past medical history, certain infections, vaccinations, your jobs, if you were taking medicines or pills, or had a lot of sun exposure, or used tobacco. This information will not be given to your parents unless it has an important impact on your health.

4) If you are 7 -17 years old you will spend about an hour answering questions about whether you had difficult events during a particular period in your life, and whether you have used tobacco. This information will not be given to your parents unless it has an important impact on your health.

5) Depending on your age and weight, you will have up to 6 tablespoons (90 ml) of blood taken for tests to try to determine why some people get rheumatic disease and some do not. The amount of blood drawn will be a safe amount. We will also ask you to urinate (pee) into a special cup the first thing in the morning so we can do tests on your urine.

The tests that will be done on your blood or urine include studies to determine how your blood cells work differently from those in your brother or sister, if you have proteins in your blood that can make you sick, if you have had certain infections and if your mother's cells are still in your blood from when she was pregnant with you. Some of your blood samples will be stored and used for studying DNA (the material that you inherit from your father and mother), and some DNA will be stored for future research. It is possible we may identify parts of DNA called genes that make you or others in your family more likely to get these rheumatic diseases. If you have some of these genes predisposing to these diseases, then you may have difficulty obtaining insurance in the future. We will provide any important results of your studies to your doctor, if it is important for them to know this information to take better care of you.

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 expert in the treatment of this infection. Some of your blood and urine 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.

Other tests not listed may be recommended to help plan the best treatment for you if you are found to have a rheumatic disease. For all of the tests, you and your parent or guardian will be consulted in advance, given full information, and asked to approve them. If you or your parent or guardian does not approve of any of these tests, they will not be done.

Your parents will be asked to tell your doctor if you have any important change in your health or if you develop new rheumatic diseases. If your condition significantly changes, we will ask your parents to have you evaluated and possibly to collect more blood and urine and to fill out more forms about what may have made you sick.

You can ask your parents or your nurses or doctors at NIH about your condition, what they are doing to you and what plans they have for you at any time.

PATIENT IDENTIFICATION**CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

STUDY NUMBER: 03-E-0099

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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 have agreed to have a doctor exam you, to have blood drawn and urine collected, and answer questions about how you feel and about other parts of your history. You can change your mind later if you say yes now. Just tell us that you don't want to take part any longer.

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: _____