

UNIVERSITY OF XXXXXXXXXXXX

RESEARCH SUBJECT

INFORMED ASSENT FORM FOR MINORS

Protocol Title: International Myositis Classification Criteria Project (IMCCP)

Principal Investigator: xxxxxxxx

Emergency Contact: xxxxx

Why am I being asked to volunteer?

You are being invited to participate in a research study to learn more about myositis, a rare muscle inflammatory condition, and how we can diagnose this condition better. You are being asked to participate since you have dermatomyositis, polymyositis, or another form of myositis, or you have an illness that mimics myositis. You meet the requirements for this study and thus are being asked to volunteer for enrollment. Your participation is voluntary which means you can choose whether or not you want to participate. This study may not help you directly, but by participating in the study, others with similar problems may be helped.

What is the purpose of this research study?

The purpose of this research study is to develop ways of diagnosing patients with myositis.

How long will I be in the study? How many other people will be in the study?

You will be asked to participate in this study one time. If you agree to participate, your doctors will conduct a review of your medical records and collect information about the clinical features of your illness, blood laboratory test results, imaging results, heart and lung test results, EMG results, and muscle or skin biopsy results. You will not be asked to do any additional testing; your doctors and their research assistants will only review your medical record containing the results of the testing you have previously undergone and use this information for the research study.

What am I being asked to do?

We would ask that you permit us to review your medical records at the Hospital of the University of XXXXXXXXXXXX to better understand the specifics of your illness, as outlined above. We may also ask for written consent to contact your other health care practitioners to discuss this study with them and to obtain more extensive medical records than what is now contained in your chart at the Clinics of the Departments of XXXXXX (Dermatology and Rheumatology).

What are the possible risks or discomforts?

There are no health risks associated with the study, since you are not participating in any new tests.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

Given the relative rarity of myositis, there is a general lack of knowledge about the best ways to diagnose these conditions. This study may not help you directly, but by participating in the study, others with similar problems may be helped.

What other choices do I have if I do not participate?

The alternative for this study is not to participate. There is no known real risk in not participating.

Will I be paid for being in this study?

There are no payments being offered for participation in this study. There will be no costs to participate in this study.

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: _____

Signature of Investigator: _____ Date: _____