UNIVERSITY OF XXXXXXXXXX
RESEARCH SUBJECT
INFORMED CONSENT FORM

Protocol Title: International Myositis Classification Criteria Project (IMCCP)

Principal Investigator: xxxxxxxx

Emergency Contact: xxxxx Xxxxx

Why am I being asked to volunteer?

You are being invited to participate in a research study. Since you have been diagnosed with dermatomyositis, polymyositis, inclusion body myositis, 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. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study and discuss the consent form with you over the phone. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to give verbal consent that you understand the risks and benefits of this study. We may ask for your written permission to obtain additional medical records from your other health care practitioners.

What is the purpose of this research study?

The purpose of this research study is to develop uniform criteria for diagnosing patients with myositis and its subsets. Currently there is no consensus on which criteria should be used for the diagnosis of these patients. This is causing a lack of progress in myositis research.

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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 study results, EMG, and muscle or skin biopsy results. Because of the large number of patients with a wide number of medical conditions, this study is expected take several years to complete. Up to 60 patients at the University of Xxxxxxxxxx's Departments of Dermatology, Rheumatology or Neurology diagnosed with myositis or with mimicking conditions will be included in this study. We do not expect more than 2 000 people to be included in the study from all over the world.

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 Xxxxxxxxxx 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, Rheumatology or Neurology).

What are the possible risks or discomforts?

Since there is no intervention taking place with this study and no drug or device being administered, there are no health risks associated with the study.

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 will be part of an international initiative to further clarify the best ways to diagnose myositis and its subsets and distinguish it from other health conditions.

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.

Will I have to pay for anything?

There will be no costs to participate in this study.

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What happens if I am injured or hurt during the study?

If you have a medical emergency during the study you may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Xxxxxxxxxx.

Since there are no procedures associated with this study, financial compensation is not available. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all information has been collected. This study may also be stopped at any time by the study Doctor or the study Sponsor without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, has decided to stop the study.
- If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

The investigator and staff involved with the study will keep your personal health information collected for the study strictly confidential. Please refer to the separate "Confidentiality & Privacy Rights" document that explains more specifically how your personal information will be protected.

Who can I call about my rights as a research subject?

If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with the Principal Investigator listed on page one of this form. Concerning your rights as a research subject, you may also contact the Office of Regulatory Affairs at the University of Xxxxxxxxxx by calling xxxxxxxxx.

When you verbally consent to participate in this study, you are volunteering to take part in this research study. This means that you have listened to the consent form, your questions have been answered, and you have decided to volunteer. Your verbal consent also means that you are permitting the University of Xxxxxxxxxx Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Xxxxxxxxxx Health System and the School of Medicine to disclose that personal health

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information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Xxxxxxxxxx Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

_____
Name of Subject (Please Print)

_____ _____
Name of Person Obtaining Consent (Please Print) Signature Date

For Use With Authorized Representative Signature

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____
Authorized subject representative **[print]**

Provide a brief description of above person authority to serve as the subject's authorized representative.

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