University Of Xxxxxxxxxx
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: International Myositis Classification Criteria Project (IMCCP)
Principal Investigator: Xxxxx

***Co-Investigators:**
Xxxxx

You have agreed to participate in the study mentioned above and have verbally agreed to a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. This authorization form gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document 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 information to outside organizations or people involved with the processing of this study.

What personal health information is collected and used in this study?

The following personal health information will be collected and used for research during your involvement with this research study, but no personal identifiers will be shared with collaborators outside of the University of xxxxxxxxxx Health System and the School of Medicine when the data is shared with the International Myositis Classification Criteria Project or the National Institutes of Health (NIH):

- Name
- Address
- Telephone number
- Family medical history (history of autoimmune diseases, muscle disease, etc.)
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Clinical muscle variables (muscle pain, tenderness, atrophy, etc.)
- Clinical skin variables (heliotrope rash, Gottron's papules, erythema of neck, periorbital edema, etc.)
- History of episodic weakness, arthritis, polyarthralgia, unexplained fevers, peripheral neuropathy, interstitial lung disease, dysphagia or esophageal dysmotility, objective improvement in muscle strength after corticosteroids or other immunosuppressive therapy
- Results of muscle biopsy, EMG, EKG, MRI if previously performed
- Results of laboratory variables if previously performed (CK, LDH, LFTs, serum aldolase, ESR, CRP, ANA, anti-RNP, anti-La, anti-Ro, anti-Sm)

Why is your personal health information being used?

Your personal contact information is important for the University of Xxxxxxxxxxxxxxxxxxx research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other University staff associated with the study)
- The University Xxxxxxxxxxxxxxx Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of XxxxxxxxxxxxxxxOffice of Regulatory Affairs
- The University of Xxxxxxxxxxxxxxx Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Xxxxxxxxxxxxxxxx and the University of Xxxxxxxxxxxxxx Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the University of Xxxxxxxxxxxxxxxx Health System and the School of Medicine, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, your personal health information, including the results of the research study tests and procedures, but excluding your name, address, or other personal identifiers, may be disclosed to the other collaborators that comprise the International Myositis Classification Criteria Project (IMCCP), including investigators at the Karolinska Institutet in Stockholm, Sweden and Oregon State University.

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of Xxxxxxxxxxx Health System or School of Medicine the information may no longer be covered by the federal privacy protection regulations.

- In all disclosures outside of the University of Xxxxxxxxxxx Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.
- In records and information disclosed outside of the University of Xxxxxxxxxxx Health System and School of Medicine, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

How long will the University of Xxxxxxxxxxx Health System and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of Xxxxxxxxxxx Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the University of Xxxxxxxxxxx Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

If requested, you will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study and a copy of 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.

By verbally consenting to the above document you are permitting the University of Xxxxxxxxxx Health System and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

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Subject's Name **[print]**

_____	_____	_____
Person obtaining authorization **[print]**	Person obtaining authorization Signature	Date

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

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Authorized subject representative **[print]**

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

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