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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Myositis Patient Centered Tele-Research (My PACER)

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SOURCE OF SUPPORT: NIH

University Of Pittsburgh Institutional Review Board
Approval Date: 4/29/2019
Renewal Date: 2/5/2020
IRB #: PRO17120352

It is very important that you read and understand the following research study information. Please feel free to ask the study doctor or the research staff any questions that will help you understand the study and what you are expected to do. Before you agree to take part in this study, you may first discuss it with a family member or your family doctor.

Why is this research being done?

The first aim of this study, called Myositis Patient Centered Tele-Research (My PACER), is to be able to reach a broader range of myositis patients across the country through the use of technology and tele-medicine in myositis research. Participants will be recruited from all over the United States to join the study by using our study app and/or website or through our rheumatology clinics. The goal of the study is to evaluate ways to accelerate recruitment in research, collect data remotely and follow up patients using telemedicine approach without geographical restrictions. The data from both the traditional in clinic research methods (center based research) and the novel technology and tele-medicine based research methods (tele-medicine research) will be compared to demonstrate that tele-medicine research provides an opportunity for better recruitment with uncompromised data collection and data integrity.

Given that many myositis patients have disease that responds poorly to treatment, there is a need for discovering new treatment options in myositis clinical trials. However, the current outcome measures (tools to assess improvement or not) for clinical trials in myositis have many flaws, which includes lack of assessing treatment response from the patient's perspective (patient reported outcome) as well as to assess improvement in patient's physical function. That is, patients often view things differently than their doctor and there is a need for better tools to assess the patient's perspective and physical function before and after treatment. This study will evaluate physical activity monitors as an objective outcome measure for physical function in myositis in conjunction with the NIH's physical function questionnaire (called PROMIS) completed by the patient (as patient reported outcome) to measure patient's perspective on changes in their physical function. The physical activity monitors (PAM) using a FitBit device will objectively measure the number of steps, flights of stairs, distance travelled, pattern of physical activity, total energy expenditure, etc. in the patient wearing the device. The Fitbit device is a non-invasive, commercially available fitness tracker that assesses physical activity throughout the day. The data from these physical activity monitors can be studied to see if patient's functional status improves over time with the treatment.

Who is being asked to take part in this research study?

You have been asked to take part in this research study because you have been diagnosed with either: Adult dermatomyositis (DM), adult polymyositis (PM) or necrotizing myopathy (NM).

The study will be done all over the United States by Tele-Research, and approximately 80 participants from all parts of the country will be enrolled through our My Pacer mobile app and/or website. It will be coordinated through the University of Pittsburgh.
This study will also be conducted at two clinic based centers, the University of Pittsburgh and Cedars Sinai/Attune Health Study Center. Approximately 40 participants will be enrolled between both centers.

What procedures will be performed for research purposes?

Before any study procedures are done, you will be able to read the details of the study and review this consent form. If you have any questions, you may call the study staff, and they will answer anything

about the study and what you are being asked to do. If you decide to participate you will be asked to sign this consent form and you will be able to revisit it at any time during the study from your dashboard. After your consent, the study team will review your screening procedures to determine your eligibility. If your eligibility is confirmed, you will receive a notification about your entry to the study, and you can begin the assessments for the baseline visit.

Screening Assessment:
A screening assessment is performed by the study doctor to see if you qualify for the study. Procedures to determine if you are eligible to take part in a research study are called "screening procedures".

1. Screening involves the collection of your information and review of your medical record. We will obtain the following information: your diagnosis, age, past medical history, diagnostic procedures, and results from blood tests that were already done as part of your clinical care. HIPPA authorization for release of your medical record will be obtained in a separate form.

2. You will be notified if you are rejected or accepted to the study.

Baseline Assessment:
If you qualify for the study, the following baseline procedures will be completed as part of the research study. The baseline assessment will be conducted from your home through the mobile app/website as well as an audio-video conference with a study doctor through tele-medicine.

1. You will self-perform a series of physical function tests at home to assess how far you can walk and how you get in and out of a chair, based on the instructions given to you. You will record the results on the My Pacer App/website. These tests take approximately 10 minutes.

2. You will be asked to complete questionnaires that assess your current and past disease related symptoms, level of myositis disease activity, and daily physical activities. These questionnaires usually take approximately 25-30 minutes to complete and will be done using this My Pacer App/website.

3. A study doctor will review your medical record and obtain any disease specific clinical laboratory or procedure results that you may have had done as part of routine care.

4. The study team will conduct a secured audio-video conference with you to complete questionnaires assessing your disease activity based on all the information gathered from you as well as from your medical records.

5. You will be asked to wear a small monitor (Fitbit device) around your wrist. The device will measure your physical activity behaviors over the course of the next 7 days. The research staff will mail you a Fitbit device after your acceptance to the study. The activity monitor must be worn for up to 24 hours/day for 7 days a month for 6 months (exceptions include daily activities of bathing, swimming, etc.).

6. You will also be asked to complete a usage log of the dates and times that you wear your Fitbit device during the 7-day period.

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Month 1, 2, 3, 4 and 5 Assessments

For months 1 - 5 assessments, you will **not** be required to communicate with a study doctor for evaluation. You will complete the tests and questionnaires as normal on the My Pacer app/website.

1. You will be asked to complete questionnaires that assess your current and past disease related symptoms, level of myositis disease activity, daily physical activities. These questionnaires usually take approximately 25-30 minutes to complete and will be done using My Pacer App/website.

2. You will self-perform a series of physical functional tests at home to assess how far you can walk and how you get in and out of a chair, based on the instructions given to you. You will record the results on the My Pacer App/website. These test stake approximately 10 minutes.

3. In between study visits you will receive a reminder notification from the app on when to complete your monthly questionnaires.

4. You will be asked to wear a PAM device called Fitbit which can be worn on your wrist. You will be asked to wear the device for 7 days for up to 24 hours a day. You can remove the device while bathing/showering or other water related activities. The device should be worn approximately the same time of month each month while you are in the study.

5. You will also be asked to complete a usage log of the dates and times that you wear your Fitbit device during the 7-day period.

6. You will be asked to charge the Fitbit device each month when you are done wearing it.

Month 6 Assessments

The final month 6 assessments will be conducted as normal, but you will also complete an audio-video conference with a study doctor through tele-medicine.

1. You will be asked if you have changed or added any medications and if you have had any negative experiences since the last study assessment.

2. You will self-perform a series of physical function tests at home to assess how far you can walk and how you get in and out of a chair, based on the instructions given to you and record the results on My Pacer App/website. These tests take approximately 10 minutes.

3. You will be asked to complete questionnaires that assess your current and past disease related symptoms, level of myositis disease activity, and daily physical activities. These questionnaires usually take approximately 25-30 minutes to complete and will be done using My Pacer App/website.

4. The study staff will review your questionnaires, functional test results, and Fitbit Monitor logs from your visits.

5. Study doctor will review your medical record and obtain any disease specific clinical laboratory or procedure results that you may have had done as part of routine care.

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6. The study team will conduct a secured audio-video conference with you to complete questionnaire assessing your disease activity based on all the information gathered from you as well as from your medical records.

7. You will be asked to complete a usage of the dates and times that you wear your Fitbit device during the 7-day period.

8. At the end of the study you may be randomly selected for a telephone interview by an experienced researcher about your perspectives on clinical studies and trials in myositis. You can choose to participate in this interview (typically 30 minutes) and it will be conducted at a date and time convenient to you. You may also be contacted for future myositis studies or clinical trials.

How will data be transferred from the PAM device?
The Fitbit device will contain only de-identified data. Data will be extracted from this device in one of the following ways: 1) You will be asked to download a Fitbit application to your smartphone if you have one and the data will be synced at set times via a Bluetooth connection to the Fitbit website OR 2) if you do not have a smartphone you will be asked to download the Fitbit application to your computer and plug the device into the computer at the end of each period of use to transfer the data to the Fitbit website. The study center will create the de-identified Fitbit accounts on the Fitbit website when you are enrolled in the study. You will be provided the account login information to sync the device after each period of use during the course of the study.

All of the data transferred from the device will be stored on a secure file server located in the Department of Medicine at the University of Pittsburgh. Only study personnel that have been assigned access to the secure file will be able to view your PAM device data.

The Fitbit device must be returned to the study center at the completion of the study or in the event of early termination.

What are the possible risks, side effects, and discomforts of this research study?
• **Breach of Confidentiality:** Data collected online has the potential risk of being disclosed outside of the research context. However, a data security plan is developed and reviewed by the University of Pittsburgh Information Technology department to ensure all required federal and local safeguards are implemented to reduce risk to the subject. The safeguards include secured data sharing and are only accessible by individuals on the intranet, password protection, separate collection of identifiable information, data stored at University of Pittsburgh secured server with all possible safety measures, etc. No identifiable data will be entered into the database for either cohort. The identifiable demographic data will be stored in a separate database from the research data. All other research data will be entered with the assigned study code. Our database is password-protected and is housed on University of Pittsburgh secured server and has limited access via a network firewall.

Data that is transferred from your PAM device will not contain any identifiable personal information. The data will be stored on a secure network server located in the Department of Medicine, Division of Rheumatology.

• **Limited information as to whether consent was informed:** Due to the consent being obtained electronically for the TRC, the investigator might not know whether research participants comprehend

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important information about the study. To prevent this, the study subject will be encouraged to call study coordinators for any questions regarding the study before and/or after consenting. Moreover, patients will be queried with a series of question before signing consent to access their understanding of the study procedures.

• **Limited monitoring of a research subject's clinical status over the Internet:** You might assume that study doctors are monitoring your self-reported data on an immediate basis and not seek medical attention for any deterioration in your condition. To prevent this, the study team will discuss in advance, procedures that you should follow if symptoms worsen or if they face an emergency. Subjects will also be informed how frequently the data will be checked. In case of any significant adverse event and/or deterioration being noted, the patient and the patient's myositis physician will be notified to take further action. Remote audio-video visits with the site investigator will also reduce this risk, as it provides a one-on-one interaction with the research subject.

• **Functional testing:** You may experience fatigue or shortness of breath during functional testing depending on your baseline health status. You should stop the test in case you experience significant fatigue or shortness of breath.

• **Physical Activity Monitor Use:** There is the possibility of minor skin irritation associated with wearing the physical activity monitor (PAM) if it is in contact with the skin. However, it is typically worn over clothes, which will prevent any skin irritation.

• **Patient reported outcomes and questionnaire:** You may experience mental and/or physical fatigue when completing the PRO measures on paper, tablet, app or website. Note, you can take a break while doing these questionnaires and do it at a convenient time and place for you.

• **Patient interviews:** You might experience anxiety regarding being interviewed about your experience and perspective about the study and future myositis clinical trials. Only subjects who agree will be interviewed at the date and time convenient to them. Interviewers will ask questions regarding your own thoughts and perspective, in the most comfortable way possible. You can refuse to answer any particular questions. The individual responses remain anonymous to study investigators and only collective themes or attributes are reported and not individual responses. Interview files will be identified by a coded patient number, not by name. Interview files will be stored on secured University of Pittsburgh drives accessed through password-protected computers in locked offices. As audio files are transcribed, we will anonymize them. That is, if you say your name, where you live, or any other identifying information, we will remove that from the transcript. After the transcript is produced and checked for accuracy, we will delete the original audio file. You may choose to not answer a question or to stop the interview at any time.

What are the potential benefits from taking part in this research study?
There is no direct benefit to you for participating in this study. It is hoped that the information gained from the study will be beneficial to myositis patients in the future. Because of your participation, there may be advancement in knowledge about dermatomyositis, polymyositis and necrotizing myopathy.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if any new information (either good or bad) develops during the conduct of

this research study which may cause you to change your mind about continuing to participate. If new information is provided to you, your consent to continue participation in this study will be re-obtained.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study?

You or your insurance will not be billed for any research procedures conducted as part of this study. These procedures include: physician assessments, audio-video conferences, PAM devices, Mobile app or website use, patient interviewers and all other study related costs will be paid by the study except where noted below. You and/or your insurance will be billed for standard of care costs (not study related) for clinic visits that you do with your treating or primary doctors. You will be responsible for costs not covered by your insurance provider that are done as part of standard of care for your disease by your treating or primary doctors. You will be responsible for any applicable co-pays, co-insurances, and deductibles.

Will I be paid if I take part in this research study?

You will receive $75 on completion of the 6-month study.

Who will pay if I am injured as a result of taking part in this research study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by local hospitals. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research study?

Any information about you obtained from or for this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in locked and protected files. Your identity on these records will be indicated by a code number, rather than by your name, and the information linking these code numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release). The University of Pittsburgh policy requires that all research records be kept for a minimum of 7 years following the end of a research study; however they may be kept indefinitely.

In unusual cases, your research records (including your identifiable medical information) may be released in response to an order from a court of law. Also, if the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law."

At the end of this research study, data (information) and your signed consent document will be stored in a research database (RDMS – Rheumatic Disease Management System) located at the University of Pittsburgh, Division of Rheumatology so that data from different myositis research studies can be pooled together to make stronger conclusions on how to measure the symptoms of this disease. Your identity on this research data will be indicated by a code number as indicated above. Your Identifiable information will be stored separately from the main data in a secured and locked location. This RDMS database is protected by an encrypted password and is located on a secure server in the University of Pittsburgh, Department of Medicine. The

Department has two secure firewall zones in place for the server.

Will this research study involve the use or disclosure of my identifiable medical information?
We are also requesting your authorization or permission to review your medical records for this study. This research study will involve the recording of myositis related medical information from your hospital and/or other (e.g., physician office) records, for example muscle biopsy or muscle enzyme results, etc. The information that will be recorded will be limited to information concerning your myositis. This information will be used for the purpose of determining whether you meet the conditions for participation in this study, to compare your earlier test results to the findings from this study, and if possible, to use your previous exam results in place of, or in addition to, some of the exams needed for this study. **We will obtain the following information:** your diagnosis, age, past medical history, diagnostic procedures, and results from blood tests that were already done as part of your clinical care. As part of this research study, none of the information that we obtain from you will be placed into your medical records held at UPMC. The medical records received will be stripped of your personal identifiers before it is stored in our secured database.

Your medical information, as well as information obtained during this research study, in a de-identified manner, **may be shared** with other groups, possibly including authorized officials from the Food and Drug Administration, the study sponsor, and the University of Pittsburgh Research Conduct and Compliance Office.

Authorized representatives of the sponsor of this research study, *NIH*, may review and/or obtain your de-identified medical information for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable medical information, UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

Authorized representatives of the U.S. Food and Drug Administration may review and/or obtain your identifiable medical information for the purpose of monitoring the accuracy of the research data. While the U.S. Food and Drug Administration understands the importance of maintaining the confidentiality of your identifiable medical information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the U.S. Food and Drug Administration.

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable medical information for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

Your study related data **may be shared** with external sites or investigators for further research studies. The external sites may include national repositories or registries and institutions and investigators not affiliated with the University of Pittsburgh. If your data is sent to external sites, a unique identifier will be assigned. Your name or any other identifiable information will be removed.

We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

May I have access to my medical information that results from my participation in this research study?
No information resulting from your participation will be included in your medical record.

Is my participation in this research study voluntary?
Your participation in this research study (including your authorization to allow the researcher to review your identifiable medical records) is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your doctor may be an investigator on this study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

You can, at any time, withdraw from this research study; you can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. No guarantee is made as to the results of your participation in this study. If certain circumstances were

to occur, the physician may stop your participation in this study without your permission. These circumstances would be related to either your failure to cooperate fully with the conduct of the study, or the recognition of significant medical risks associated with your continued participation in this study. If your participation in this study is stopped, the reasons will be discussed with you.
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This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____
Printed Name of Participant

_____ _____
Participant's Signature Date