UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA
AUTHORIZATION FORM

Protocol Title:	Ultrasound to Enhance Treat-to-Target in Rheumatoid Arthritis: A Cross-Sectional Study
Principal Investigator:	Michael George, MD, MSCE Perelman Center for Advanced Medicine 3400 Civic Center Blvd., 1 South Pavilion Philadelphia, PA 19104
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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to see if ultrasound can be used to better determine whether joint inflammation is present when patients with rheumatoid arthritis have significant symptoms but few swollen joints. Patients with elevated disease activity scores but few swollen joints will be eligible for this study.

If you agree to join the study, you will be asked to complete the following research procedures:

- Complete surveys
- Have an ultrasound of the hands and wrists (visit lasting approximately 1 hour)

Your participation will last for about 4 weeks, or until the time that your ultrasound visit is complete. The data collected will be kept for up to five years or until the study is complete.

No direct benefits are expected from this study. The most common risks of participation are a small risk of disclosure of personal health information.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you have rheumatoid arthritis and you are followed in the rheumatology clinics at the University of Pennsylvania Health System. Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. 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 they will give you this consent form to read. 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. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this research study is to determine whether ultrasound technology can improve treatment decisions for patients with rheumatoid arthritis who have elevated disease activity scores.

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

The study involves completing surveys and having one ultrasound imaging visit, which should last about an hour. You will be in this study for about 4 weeks. After the ultrasound visit, your participation in the study will be complete. We plan to enroll 40 patients with rheumatoid arthritis into this study over 1-2 years.

What am I being asked to do?

You are being asked to have an ultrasound scan of your hands and wrists and to complete questionnaires.

Ultrasound is a painless, non-invasive test that uses sound waves to create images of the inside of your body. A hand-held probe is pressed against your skin to produce the images.

Your rheumatologist evaluates your disease activity during your clinic visit by examining your joints and asking you to rate how your disease is doing. If your disease activity level is within a range that is eligible for our study, we will ask you to complete five short questionnaires after your clinic visit and we will schedule an ultrasound.

These questionnaires will assess things like how your arthritis affects your daily activities, pain levels, and degree of fatigue. The research coordinator will also gather data from your electronic medical record in the University of Pennsylvania Health System, including demographics, details about your rheumatoid arthritis, and other medical problems.

The research coordinator will contact you to schedule your ultrasound visit. The coordinator will meet you on the day of your ultrasound and accompany you to the musculoskeletal ultrasound department or rheumatology clinic space to complete the scan of your hands and wrists. The ultrasound results will be shared with your rheumatologist.

Once your scans are done, your involvement in this study is complete.

What are the possible risks or discomforts?

Ultrasound: Ultrasound imaging is generally considered safe when used appropriately by trained healthcare providers and does not involve radiation. The ultrasound has no known risks or side effects. You may have very minor discomfort from pressure on the skin from the ultrasound probe

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?

The ultrasound scans generated in the study may be used by your rheumatologist to help make decisions about your treatment options. In addition, this study may help us understand how using ultrasound can improve treatment recommendations in other patients with rheumatoid arthritis.

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

You have the choice to not participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. You may choose not to participate and continue with the routine care provided by your rheumatologist.

Will I be paid for being in this study?

If you are eligible for the study and complete all necessary procedures including the ultrasound, you will receive $100 for your efforts after your ultrasound scan is complete.

Payments are made using the Greenphire ClinCard system. The Greenphire ClinCard is a reloadable prepaid card. In order to be compensated for your participation in this study, you must provide your Social Security Number. This information will only be used for reimbursement purposes and will not be shared with anyone outside of the research team. Please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

You will not have to pay for any research procedures or tests that result from participating in this study, including the ultrasound scan.

You are still responsible for any deductibles or applicable co-pays for other routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for health care. However, the results will be put in your medical record.

What happens if I am injured from being in the study?

It is important that you tell the Principal Investigator, Dr. Michael George, if you feel that you have been injured because of taking part in this study

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

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

This study is expected to end after all participants have completed all visits, and all

information has been collected. This study may also be stopped at any time by your physician without your consent because:

- The Principal 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 study Principal Investigator has decided to stop the study.
- If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

Additional electronic records will be stored on a secure server maintained by University of Pennsylvania, Perelman School of Medicine. Your name and any directly identifiable information will be removed and replaced with a unique study identification number. Only the Principal Investigator and research coordinator will have access to written files and the computerized database that include your name and any other identifying information.

Internal monitors from the University of Pennsylvania OCR, a research oversight committee, may inspect study records for quality assurance.

What may happen to my information collected on this study?

Your information will not be stored or shared for future research purposes after the project is completed.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

What information about me may be collected, used or shared with others?

The information collected for this study will include:

- Name, address, email, telephone number, date of birth
- Medical record number
- Personal and family medical history
- Results from physical examinations, tests, or procedures (including dates)
- Social security number (to pay you)

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and the study team

- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?

No one outside the School of Medicine will be able to receive your information.

The U.S. Office of Human Research Protections may be allowed to view your information.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page 1 of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

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

IRB Approval from 11/23/2021 to 11/22/2022