

Informed Consent Document
2/7/2017 Version 2.0

Title: ArthritisPower Research Registry

Protocol No.: ArthritisPower

Sponsor: Global Healthy Living Foundation with initial start-up funding from PCORI (the Patient Centered Outcomes Research Institute). PCORI receives its funding, and in turn, issues contract awards to patient organizations or universities. PCORI'S funding was established by Congress through the Patient Protection and Affordable Care Act of 2010.

Investigator: William Benjamin Nowell, MSW, PhD (Director of Patient Centered Research at the Global Healthy Living Foundation)

Sub Investigators include: Jeffrey Curtis, MD, MS, MPH (University of Alabama at Birmingham, Division of Clinical Immunology and Rheumatology) and Seth D. Ginsberg (Co-Founder and President, Global Healthy Living Foundation).

Telephone: 845-348-0400

What is the purpose of ArthritisPower?

We are asking you to take part in the AR-PoWER (ARthritis Partnership With Comparative Effectiveness Researchers) "ArthritisPower" research study (the Registry). As explained in more detail below, a registry is a collection of information about individuals, often those who have a specific diagnosis or condition, and the individuals voluntarily share information about themselves to the Registry.

The purpose of this Registry is to use the ArthritisPower™ mobile and web-based computer application (the App) to collect information from patients like you who have been diagnosed by a physician and are living with chronic conditions involving joints, bones, and skin. The App is only available in this Registry study.

The information collected in this Registry study:

- 1) May be used by you to help track your health and how you are feeling. You can use your username and password to access your information through the mobile ArthritisPower App on your smartphone, or on the web at www.arthritispower.org.
- 2) Will be stored indefinitely (forever) and will be used for future research studies unless you request to withdraw from the Registry or until the Registry is permanently closed. The information will be used by researchers to help them gain insight about patient experiences with medications, outcomes, and quality of life. Also, in the future, scientists may want to study new treatments, and may wish to invite patients to join a clinical trial. The Registry can help interested participants to connect with these scientists. (It will be your voluntary decision whether to participate in a clinical trial.)

- 3) Will be used to evaluate the effectiveness of use and patient satisfaction with the mobile ArthritisPower App. The researchers will also use information collected during this research to continuously build a set of mobile and internet based applications to help patients better track their health.

The Global Healthy Living Foundation (GHLF) is not a health care provider, and ArthritisPower is not a mobile medical app; the intended use of the app is not for the diagnosis of a disease or the cure, mitigation, treatment, or prevention of disease, nor is it intended to affect the structure or any function of the human body. Instead, as a Registry bringing together information, we will collect information about you during your use of the App throughout your participation in the Registry and also by sending you surveys and questionnaires to complete. In addition to the information that you enter into the "survey tools," we would also like your permission to use information from your electronic health records that are available at some clinical laboratories, pharmacies and/or electronic health information that is available from your health insurance company or plan. With your permission, we also want to be able to collect information that you can share with us from your own health devices or trackers, like a Fitbit or Jawbone, and information from your phone itself (your geolocation and associated information).

Not all of these features are currently available with the App. However, we will alert you throughout your participation in the Registry when the potential uses of the App are expanded, so that you can opt in to participate in those uses if you voluntarily choose to do so. We plan to combine the electronic data with the other information you voluntarily provide to us and store it in the patient research registry.

You will be asked to sign this electronic consent form to be part of the Registry, and this consent form combines a consent to participate with a Health Insurance Portability and Accountability Act ("HIPAA") authorization and is consistent with applicable state law. You may already be familiar with CreakyJoints, GHLF's online community of people affected by arthritis or related conditions. We hope that more than 20,000 of our CreakyJoints members will join the Registry. Please note that the Registry is only intended at this time for residents of the United States and United States territories who are nineteen (19) years or older (for Puerto Rico residents, you must be 21 years or older to participate).

What is a research registry?

A patient research registry is a place to store detailed information about patients with a specific disease or condition. In this case, the ArthritisPower Registry is for patients with conditions involving joints (e.g. arthritis), bones, skin, and disorders of the immune system. Establishing the Registry addresses many important needs. First, scientists studying these conditions need accurate information directly from patients to understand how people are affected by a condition and its treatments. The Registry will use already-collected information for future research studies to better understand how different treatments lead to better or worse outcomes for arthritis patients.

If you have any cultural or religious beliefs or preferences that prohibit certain types of future research, please discuss these with the investigator before agreeing to participate in the registry study.

What will I be asked to do?

You may have heard about the Registry in a number of ways, for example, through the CreakyJoints Facebook page or website, a flyer at your doctor's office, or at a community outreach event. You can discuss the Registry with one of the study investigators, Ben Nowell, at the Global Healthy Living Foundation (GHLF) at 1-845-348-0400 or email at feedback@arthritispower.org if you have any questions.

Once you have enrolled in the Registry, we would like you to complete some online surveys in which you will report data about your health. In the future there may be additional surveys that we will ask you to answer. All the surveys are optional. You can choose to NOT complete the surveys and still participate in the Registry.

Among the lab tests that may be available to you now or in the future is the VectraDA biomarker test, provided by Crescendo Biosciences. The VectraDA lab is a blood test, which would be ordered by your doctor, that measures RA disease activity. You may authorize us to obtain your VectraDA test results in order to add them to the information about you in the Registry. The App uses the IDology verification service to verify your identity, to make certain that we are supplementing the correct person's information in the Registry. If your doctor has already received and interpreted your test results, the ArthritisPower app may be able to display to you a copy of your VectraDA lab results. If you have not had the VectraDA lab, then the App will show you a message stating "No lab results available". There may be other circumstances where we ask you to verify your identity as part of our privacy and security safeguards. Please note the App is not a personal health record or electronic medical record but is a way for you to better track your health and how you are feeling, including for purposes of research.

You may or may not be asked to participate in future research studies. In some of the future research studies, the researchers may ask that you permit us to obtain test results of blood specimens as ordered by your doctor or self-requested by you from a laboratory (as permitted by state law), to gather more information about rheumatic diseases. You will be asked to sign a new and separate informed consent for any study or supplemental research information that involves blood tests or blood collection. The amount of blood sample needed will depend on the type of laboratory test you are voluntarily undergoing. You will always be asked if you would like to participate in these additional projects and you do not have to participate in the blood collection or testing projects to stay in the Registry. You may also in the future be asked if you would like to be contacted by other researchers about participating in studies or clinical trials.

What types of information will be collected in the Registry?

- 1) Health-Related Data: Through surveys that capture information about how you are doing, pain you experience, mobility, and similar types of data, you will be able to better track your health and provide information to support research that helps others with your same health condition.

- 2) **Personal Information:** We need to know some information about you in order to build tools and offer useful resources for you, and also to support patient research. For example, we are asking for your name, date of birth, mailing address, email address, etc. You may choose to provide additional information, like your Social Security number, that will help us confirm that your information from your health care providers or health insurance claims is correctly “linked” (supplemented) to your individual Registry information. Your Social Security number is a unique identifying number that can allow you to access your information about your health care from your health insurance and other data sources. It is okay **NOT** to provide your Social Security number and you can still join the Registry.
- 3) **Personal Health Information:** The information you enter into the Registry will be stored in secure servers located within Amazon Web Services’ (AWS) data centers, and made available to our research partners, including Dr. Jeff Curtis, and also his research team at the University of Alabama at Birmingham Division of Clinical Immunology and Rheumatology (UAB). Dr. Jeff Curtis is a researcher working with the study investigator Ben Nowell. As noted above, your information may be supplemented by other sources of information that you permit us to receive, such as health plan data about medication use, laboratory results, and healthcare utilization and information that you choose to share with us from your own fitness trackers and other personal wearable devices.
- 4) **Electronic or Other Data Collection:** We want to help customize your experience with the ArthritisPower™ application ("the App") and bother you as little as possible. We therefore would like to capture location information and your web location (Internet Protocol address) from the mobile device on which you run the App. You can shut the location tracker off if you don't want to allow this, and that is okay. In addition, we would gather other information that helps us customize the electronic tools we are providing to better match your preferences and screen size, such as the type of online browser you use (e.g., Safari, Chrome, Explorer, Mozilla), your preferred language, and the use of "cookies" that store information on your browser. This information may be used for arranging the mobile application in the most user-friendly way, customizing your browsing experience and keeping track of the preferences of individuals using the App.

Why am I being asked for this information?

Your personal identifying information may be used to keep track of and gather additional information for you and our research partners about your health status. Here are examples of how this information might be used.

Future Research Surveys and Study Updates: Occasionally you may be contacted by email, the Internet, mail or phone to answer questions about your health condition, its treatment, or other aspects of your health. These data will be used to supplement information in the Registry and collected on the App. Your decision to participate in this future research and answer survey questions is completely voluntary.

Supplemental Data: Your health information may be supplemented from other external databases like your health plan data, administrative claims, laboratory, medical records, other patient-reported outcomes, pharmacy data, and your own fitness trackers and other personal wearable devices. You cannot participate in this study if you do not allow the researchers to collect information from your insurance companies, health plans, laboratories and doctor. These data will be used to supplement information in the Registry. These data will only be accessed by persons authorized to do so, and information stored within them is not available to the general public. Please note that this Supplemental Data, when requested, is not intended to seek HIV, AIDS, mental health, substance abuse, or genetic information about you.

Follow-up Information: If you are unable to answer questions for yourself, we would like to contact a person you have designated who could answer questions for you, such as an emergency contact or responsible party. We plan to access this person's contact information through information in your electronic health record (if/when this information is available to the researchers). This may include obtaining information about your cause of death if you should pass away while still a member of the Registry. This would be similar to a personal representative under HIPAA, such as your spouse or a health care agent designated by you. It is your voluntary decision whether to designate someone for GHLF to contact if you are not able to answer questions yourself.

Will my personal information be shared with anyone?

Based on your permission, we may request additional data about you from sources such as laboratories, pharmacies, or your health insurance company. To make sure we are obtaining your information and not someone else's information, we may share some of your personally identifying information to order to verify. Our research team will not sell or rent your personal information or personal health information to any other company or organization. We will not share information with your insurance company and not even your doctor unless you tell us that you want them to have access to this information; there is a specific place for you to note your decision below. You can still participate in the Registry if you decide not to allow the researchers to share information back to your doctor(s).

The study investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the Federal Office for Human Research Protections (OHRP) and the Schulman Associates Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. Such access will be for research purposes and/or to ensure Registry protocols are being followed and Registry participants' rights are being protected. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Who will be able to access my information?

The GHLF CreakyJoints and ArthritisPower team, Dr. Jeff Curtis, and his research colleagues at the University of Alabama at Birmingham will have permission to receive, use, and share your personal health information. For example, sometimes GHLF CreakyJoints staff would like to send information about research opportunities to people with specific conditions and this would require access to your email address and condition information. Those who oversee this project may have access to your information only if necessary including members and staff of Schulman Institutional Review Board.

Will information in the Registry be connected to other disease registries?

Yes, we plan on sharing data with other disease registries and data sources, based on your permission, but we will remove as much personally identifying information as possible before sharing. Only the minimum necessary amount of information needed to connect your data back to you will be shared or exchanged with others who already have your data. For example, regarding your lab tests, we would exchange only the minimum amount of information necessary to make sure we were receiving your lab data from your lab provider, and not receiving someone else's data. Additionally, CreakyJoints sometimes collaborates with other patient groups and research scientists to advance knowledge of arthritis and health conditions captured by the Registry. These opportunities may include sharing of Registry information with other IRB-approved registries and research initiatives. For example, the Registry is supported by the Global Healthy Living Foundation to participate in a patient-centered distributed research network (PCORnet) organized by the Patient-Centered Outcomes Research Institute (PCORI). The Registry's data will be connected with data from other registries to increase knowledge and better understand the effectiveness and safety of treatments for your condition. Information in the Registry may also be linked (supplemented) to data in other registries.

Will I be asked to provide additional information in the future?

Yes. Registries are most useful for scientific research when the information is kept up to date. Registry staff will e-mail you to inform you how/why you can contribute additional information. We may also provide a notification within the App displaying messaging regarding requests for additional information. It is your voluntary choice whether to provide additional information, and you can stay in the Registry either way.

What are the risks involved with participation, and how will my information be kept confidential?

The main possible risk to you would be a loss of confidentiality of your information. We and our research partners are committed to maintaining the confidentiality of your Registry data using industry standards of computer encryption and data security. For example, when you are providing information to the Registry from the App on your smartphone, the App will scramble the data; this is called "encryption" and will use a secure channel to send your information from the App to the Registry storage location. This technology is similar to that used for online banking through your bank's website or smartphone app. Amazon Web Services (AWS) and University of Alabama at Birmingham (UAB) computer professionals will protect the security and confidentiality of your electronic information, including through passwords, authentication and firewalls, in a HIPAA compliant environment. For example, Dr. Curtis and his research team analyze the individually identifying Registry data that you contributed and authorized; however, they do not send any identifying information about you to GHLF. Before Registry information is sent to GHLF, it is "de-identified" consistent with HIPAA, which means it does not identify you and could not reasonably be used to identify you. Once the de-identified data is sent to GHLF, GHLF has additional safeguards in place, such as firewalls, encryption, protocols, and restricted access.

Despite numerous safeguards in place, the use of any electronic communication systems such as the World Wide Web has a number of risks. We cannot guarantee that there will not be a confidentiality breach but all parties involved will use reasonable means to protect your information.

Any new important information that is discovered during the Registry and which may influence your willingness to continue participation in the Registry will be made available to you.

What are the benefits of participation?

Although the App may help you better track your health, you may not benefit directly from participating. However, the data collected in the Registry may help other patients and researchers understand how to better treat your type of condition and improve the quality of care and outcomes for patients like you. Additionally, with your permission, some Registry data can be redisclosed to your physician, and that supplemental information may assist in your doctor's care and treatment of you.

What are the alternatives to participation?

The alternative is to choose not to participate in the Registry. Your decision to not participate in this registry will not affect your membership within the CreakyJoints community.

Do I have to participate? What do I do if I want to drop out of the study?

Whether or not you take part in the Registry is your choice. There will be no penalty if you decide not to participate in the Registry. If you decide not to be in the Registry, you will not lose any benefits you are otherwise owed. You are free to withdraw from the Registry at any time. If you would like to remove yourself from the Registry, please send an email to feedback@arthritispower.org.

When a patient chooses to leave the Registry, the information already collected following initial consent will continue to be housed and used by the Registry. However, you may additionally request in writing for us to delete all your identifying information upon withdrawing from the Registry if you wish to do so. Information which would not identify you and which has already been prepared and/or combined with others' information before we received your deletion request would not be affected by your request.

Your choice to leave the Registry will not affect your relationship with us. You may be removed from the Registry if CreakyJoints chooses to permanently close it. In the event that the researchers close or stop the Registry, all participants will be notified via email, as well as through in-app notification messages.

Will participation cost me anything?

No. There will be no cost to you for joining the Registry. There is no direct cost for using the Registry App. The app does use internet data. As with any app, regular data usage rates apply when the app is being used while roaming or off of Wi-Fi service.

Will I be paid to participate in the research registry?

You will not receive any direct compensation for simply joining the Registry. However, there may be payments for participation in specific surveys or other activities you may be contacted about in the future through the Registry. It is your voluntary decision whether to participate in these surveys or other activities, whether they are compensated or not. We will always tell you clearly up front if a survey or additional research we are asking you to complete provides compensation to you. Please note, however, there is no guarantee that you will be eligible to participate in other future research surveys or that any such compensation will be available for such surveys.

Will I be told of new information or findings?

Yes. We at CreakyJoints, our parent organization the Global Healthy Living Foundation, Dr. Curtis, and our research partners will keep you up to date on new findings through the contact information that you provide to us as part of the Registry. We will tell you if new information becomes available that might affect your choice to stay in the Registry.

What about my legal rights?

You are not waiving any of your legal rights by signing this informed consent document.

Who should I contact if I have any questions?

If you have any questions about the registration process or about participation in the Registry, please contact Ben Nowell, the Principal Investigator of the research at CreakyJoints of the Global Healthy Living Foundation at feedback@arthritispower.org. You may also call Dr. Jeffrey Curtis at 205-975-2176. To inquire about your rights as a participant in the Registry, or to report problems that result from your participation in the Registry, you may contact Ben Nowell from CreakyJoints of the Global Healthy Living Foundation at (845) 348-0400 or email feedback@arthritispower.org.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

You will receive a PDF copy of the informed consent document upon signing and providing informed consent. Your signed informed consent document is available for download within your Account information on the web-based or mobile App. Please note that when you store and view the consent document on your personal electronic device, your information could be compromised in the event that your device is lost or hacked, or if you choose to share your device, password or login credentials with someone else.

[After clicking next on the screen, the user must agree or decline]

Yes, GHLF, including its agents and employees may release my email address to other researchers who are conducting studies in rheumatic diseases or who are looking for individuals to invite for other possible research studies. I understand that only my email address will be released and I may decline to participate in the additional study. I understand that whether or not I permit release of my email address to other researchers does not affect my participation in the Registry. I understand that I may revoke (cancel) this permission at any time by contacting Ben Nowell in writing at GHLF at feedback@arthritispower.org.

(agree / decline)

Please see the Authorization language below regarding release, use and disclosure of your Health Related Data, Personal Information, Personal Health Information (PHI) and Electronic or Other Data Collection, as defined in the Informed Consent form; for convenience, these categories are combined and listed as "Personal Information, Medical Records and PHI" below. This Authorization is combined with the research study Informed Consent form, as permitted by the Health Insurance Portability and Accountability Act (HIPAA) and state law. If you wish to participate in the research Registry, your participation is conditioned on (requires) the Authorization as set forth below too. However, if you do not agree to the Authorization below, you must decline participating in the Registry. Also, if you choose to receive research-related treatment as part of Registry research, this requires the Authorization below so that we can learn the results of such research-related treatment.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL INFORMATION, MEDICAL RECORDS AND PHI FOR RESEARCH PURPOSES

Participant Name:

DOB:

By signing this document, I certify that I am the Participant listed above, and I voluntarily authorize the release, use and disclosure of all of my personal, medical record and protected health information (collectively "PHI") as described below.

Information Included*: Complete medical record, health history, physical examination, condition, diagnosis or prognosis, notes, prescriptions, diagnostic test results, any reports, all images of any kind (x-rays, photographs, MRI, CT, etc.) and any and all other health information or records regarding the Individual's health or treatment, including claims, payment, and medical billing records.

***Certain PHI Not Included:** I understand this Authorization does **not** include HIV, AIDS, mental health, substance abuse, or genetic information; persons and entities relying on this Authorization should **not** include such information or records.

Persons Authorized to Make the Use or Disclosure: Any hospital, health care facility, clinic, laboratory, pharmacy, physician, nurse or any other health care facility or health care provider who has provided assessment, care or treatment to me plus any health plan, insurer or government payor who has received, paid or reimbursed health care claims by me or on my behalf. I understand that PHI also includes records disclosed to them by other health care providers or facilities who previously provided treatment to me.

Purpose; No Expiration Date: The purpose of this Authorization is to participate in the ArthritisPower research registry, for research and for other purposes as described in the signed Informed Consent form. Because this authorization is for research purposes, I understand it has no expiration date.

Photocopy or PDF permitted: A photocopy or PDF of this document will be as valid as the original Authorization. Because this Authorization is combined as part of a longer Informed Consent form, I specifically request and permit GHLF to condense a photocopy or PDF of this Authorization so it only includes the Authorization form and my signature, when submitting the Authorization to obtain medical records and PHI.

Recipients: Those who may have access to, receive and review the PHI are: the Global Healthy Living Foundation's ArthritisPower researchers and staff, Dr. Jeffrey Curtis, and the research staff at University of Alabama at Birmingham who work on ArthritisPower, and each of their permitted contractors. The PHI should be submitted to: [Jeffrey Curtis, University of Alabama at Birmingham, Division of Clinical Immunology and Rheumatology, 510 20th Street South, FOT 802D, Birmingham AL 35294, PHONE: 205-975-2176 EMAIL: \[jcurtis@uab.edu\]\(mailto:jcurtis@uab.edu\).](#)

Right to Revoke: I understand that I may revoke (take back) this authorization at any time by submitting my written request to the ArthritisPower research team at Global Healthy Living Foundation, Attn: ArthritisPower, 515 N. Midland Ave, Upper Nyack, NY 10960. I also understand that my revocation will not affect any actions taken by GHLF, Dr. Curtis or ArthritisPower researchers in reliance upon this authorization before it was received. I also understand my revocation will not affect data which has already been de-identified or aggregated with others' data before my revocation was received.

Right Not to Sign: I also acknowledge my right not to sign this document and that such refusal will not affect any treatment, payment, health plan enrollment or eligibility for benefits that I already have. However, I understand that my refusal to sign this Authorization will prevent my participation in the ArthritisPower research study Registry.

Re-disclosure: I acknowledge that there is a potential risk that the information and PHI used or disclosed pursuant to this Authorization may be subject to redisclosure by the Recipients, and no longer be protected by the HIPAA Privacy Rule. I understand that further information on confidentiality of study records is covered in my ArthritisPower consent form.

I have read and understand this Authorization and Informed Consent Form, and any questions have been answered to my satisfaction before I decided to sign this document.

Signature of participant

Date