

Research Consent Form

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

Summary of Important Information

We are asking you to participate in this research study. Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive from your doctors.

In this research study, we want to learn more about how children and young adults with rheumatic disease and their parents use an app to track their symptoms and complete surveys about their health. We hope to learn whether the app helps patients and families better understand their rheumatic disease. Finally, we are interested in exploring whether this information could be useful to provide to doctors to improve the quality of care they provide.

It is important to consider reasons why you would or would not want to participate in this research.

If you decide to join this study, the following things will happen:

- You will use the vRheum app to track your or your child's disease activity over time.
- You will answer periodic surveys about your or your child's health.

- If you are a parent, you may invite your child to track their symptoms and answer surveys if they are 7 years or older
- You may receive periodic notifications (reminders) to answer new surveys once they become available

The most important potential risks to know about are:

- By downloading the app to your phone and answering questions, other people may glimpse at your phone and realize that you or your child is enrolled in the study and may have a chronic health condition.
- If another person has access to your mobile phone and knows your vRheum app password, they may be able to view information collected, including psychological symptoms and gender identity.
- There is the potential loss of your personal health information.
- Using a device while driving can cause accidents.
- App usage may incur charges depending upon the user's mobile data plan.
- Participants may become more aware of the symptoms of their disease.
- Survey results may suggest symptoms of depression or anxiety. If your child fills out the survey and there is an indication of certain symptoms of depression or anxiety, you will receive an unencrypted email about this to the email address you provided. For participants ages 18+, you will also receive an unencrypted email about your results if surveys suggest symptoms of depression or anxiety. Unencrypted emails are sent directly to and can be opened from your personal email account. There is a potential risk of loss of confidentiality when using unencrypted email, as your email account is hosted by a third-party. Please be aware that email communication can be intercepted in transmission or misdirected.
- Although all surveys are optional, they may cause you to feel inconvenienced.
- You may lose access to the vRheum data you collected at the end of the study.

The most important potential benefits to know about are:

There are no immediate benefits from participating in this research. However, by using the app, you may develop improved self-awareness of your/your child's disease activity, symptoms, and signs, that could conceivably improve care. You will be able to view the history of your/your child's disease activity over time. By

using this data, you may provide your doctors with more accurate assessments of your/your child's health.

The study will run for several months. You will be asked to complete a daily check-in which you can do as frequently as daily, or less frequently. Every month or every few months you will be asked to complete additional surveys about your/your child's health. Each survey may take 1-15 minutes, and all surveys are optional.

You may email the study team at vRheum@childrens.harvard.edu any time you have questions about the research. You may call the Boston Children's Hospital Institutional Review Board (IRB) at 617-355-7052 if you have questions about your rights as a research subject.

You are free to decide whether or not you want to be in this research study. It is up to you. You can decide that you do not want to be in the study. You can decide to be in the study and stop at any time. If you decide not to be in the study or if you decide to stop, you will not lose any benefits to which you are entitled. If you decide to be in the research study and decide to share results with you/your child's doctors, it could change your treatment plan.

Signing this document means that you understand all the information above. If you sign this form it means that you agree to be in the study.

How are individuals selected for this research study?

You are being asked to participate in the study because you have indicated that you or your child has a pediatric rheumatic disease.

Why is this research study being conducted?

In this research study, we want to learn more about how children and young adults with rheumatic disease and their parents use an app to track their symptoms and complete surveys about their health. We hope to learn whether the app helps patients and families better understand their rheumatic disease.

Finally, we are interested in exploring whether this information could be useful to provide to doctors to improve the quality of care they provide.

Who is conducting this research study, and where is it being conducted?

The study is being led and organized by clinicians and researchers at Boston Children's Hospital. The study is funded by the Childhood Arthritis and Rheumatology Research Alliance (CARRA), a nationwide network of pediatric rheumatologists who aim to find the best methods to treat, prevent, or cure all pediatric rheumatic diseases.

How many people will participate in this research study?

The study will enroll up to 3,000 patients and their families within the United States.

What do I have to do if I am in this research study?

You will download our free study app, vRheum, from Apple's App Store or Google's Play Store. You will first confirm eligibility to enroll in the study, review study information, and sign this consent form. If you are a parent of a child age 7 or above with a rheumatic disease, you will be required to obtain assent from your child. For children ages 7-17, you will decide whether you will complete the survey on your own device, whether your child will complete surveys on your own device, or, for children ages 13-17, whether the child will complete surveys on their own device.

After enrollment, you will complete a daily check-in that will ask about your/your child's disease activity including duration of morning stiffness, location of joint swelling or pain, levels of fatigue and pain. You will have the opportunity to complete the daily check-in as frequently as daily. If you don't complete it in 7 days, you can choose to receive a notification reminder to complete the survey.

You will also complete series of surveys that will assess your/your child's demographics, overall health, medications side effects and adherence, as well as experiences with telehealth. Comprehensive surveys will assess your/your child's health every 3 months in the following domains: pain, fatigue, depressive symptoms, anxiety, physical functioning, and mobility. You will also have the

option to track several of these domains on a monthly basis, if they are of particular interest to you.

You will be able to see the results of the surveys you complete and how they change over time.

You will be in this research study for about one year, but you may stop using the app and withdraw from the study at any time.

What are the risks of this research study? What could go wrong?

There may be a risk to your privacy by joining this study. By downloading the app to your phone and answering questions, other people may glimpse at your phone and realize that you or your child is enrolled in the study and may have a chronic health condition. If someone has access to your phone and knows your vRheum password, they may be able to view your information, including psychological symptoms and information regarding gender identity. There is the potential loss of your personal health information. Using a mobile device while driving can cause accidents. App usage may incur charges depending upon your mobile data plan. You or your child may lose access to the vRheum data you collected at the end of the study.

You or your child may become more aware of symptoms of their disease. You or your child may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You or your child may become frustrated if you are asked questions during the survey that you do not know how to answer. You may not be able to answer all the questions and you do not need to answer any questions that you do not wish to answer. If you become upset at any time, you can stop the survey. Survey results may suggest that you or your child has symptoms of depression or anxiety; if so, we will offer links to mental health resources where you or your child can speak to someone about how they are feeling.

We will send you regular non-encrypted emails if your child has symptoms of anxiety or depression and completes the survey on their own mobile device. For adults 18+, we will also send you an email if your results suggest symptoms of anxiety or depression. Unencrypted emails are sent directly to you and can be

opened from your personal email account. There is a potential risk of loss of confidentiality when using unencrypted email, as your email account is hosted by a third-party. Please be aware that email communication can be intercepted in transmission or misdirected. You will receive a non-secure email to the email address you provided notifying you of this information. This means that anyone that has access to your inbox could see these results.

If you participate in this study, you acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email will be confidential.

What are the benefits of this research?

Being in this research may not help you right now. When we finish the research, we hope that we will know more about how children with pediatric rheumatic diseases and their families use a mobile app to track their symptoms over time. We will also test whether this information would be useful to treating clinicians. We hope the results of this study will help to improve the care of pediatric rheumatic diseases.

Will I receive my study results?

You will have access to results of your daily check-ins as well as results of standardized surveys, and how they change over time. We will alert participants of any publications that come from this study through the Resources section of the app.

Will my samples/information be used for research in the future?

We will gather information about you as part of your participation in this research study. The information/samples may include personal information, such as your/your child's name, email address, and birth date, as well as information regarding your/your child's pediatric rheumatic disease, measures of disease activity, and other health measures.

To advance science, medicine, and public health, we may share your information with other researchers but only after personal information that may identify you

has been removed. Your information will be labeled with a research code without identifiers that directly identify you/your child. This information may be shared without getting additional consent from you.

Are there costs associated with this research? Will I receive any payments?

There are no costs to participate in this research study. The vRheum app is free to download and use. You may incur data usage costs from your mobile carrier. You will not receive any payments by participating in this study.

If I do not want to take part in this research, what are the other choices?

Joining this study is entirely optional. If you do not join this research study, you may discuss with your healthcare team about other potential research studies that may be available.

Are there other things I should know about?

As this research progresses we may learn new information from data we have collected through other participants or from outcomes from other research studies. If this information could affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

Why would I be taken off the study early?

The research investigators may take you out of this study at any time. This would happen if:

- The research is stopped
- You are unable to complete the surveys

If this happens, the research investigator will tell you.

Other information that may help you:

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

Who may see, use or share your health information?

The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within a hospital, an insurance company, or employer would ever learn of such results.

We have applied to the National Institutes of Health for a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What should you know about HIPAA and confidentiality?

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study;
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program;

- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research;
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories and others;

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children's Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be

used for teaching purposes. However, your name or identifying information will not be used without your specific permission.

Your privacy rights

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children’s Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital’s Privacy Officer at (857) 218-4680.

Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

 I can call...	At	 If I have questions or concerns about
Investigator: Jonathan S. Hausmann, MD	Phone: 617-355-7112 Pager: 617-355-7243 [Pager #3096]	<ul style="list-style-type: none">▪ General questions about the research▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints
Investigator: Marc Natter, MD	Phone: 857-218-3531	<ul style="list-style-type: none">▪ General questions about the study▪ Research-related injuries or emergencies

Institutional Review
Board

Phone: **617-355-7052**

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- Any research-related concerns or complaints
 - Rights of a research participant
 - Use of protected health information.
 - Compensation in event of research-related injury
 - Any research-related concerns or complaints.
 - If investigator/research contact cannot be reached.
 - If I want to speak with someone other than the Investigator, Research Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily provided to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).