Medical Trial: Appraising Clinical Trial Experiences of Rheumatoid Arthritis Patients

An informed consent form for participants in Power Clinical Trials observational clinical trial.

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Rheumatoid Arthritis Observational Study Overview

This document is formally requesting you to engage in a medical research study (clinical trial) intended to determine how a range of circumstances encountered during the clinical trial enrollment process will affect your capacity or desire to participate in, and then complete, your clinical trial. The findings of this observational study will be anonymously collected and evaluated in order to uncover trends in the patient experience that regularly result in lower completion or enrollment rates.

This clinical trial is an observational study, which means that your treatment regimen will not be altered or determined if you opt to participate. Being a participant in medical research differs from being a patient. This paper is a written description of the conversation you had with our recruiting coordinators and site employees in person. It is also intended to serve as a useful reference for you as a participant as you progress through the clinical trial procedure.

Important notes about medical trials

1. Participation is completely voluntary, and you may opt out at any moment. This is not unusual.
2. Because this is observational research, your participation will have no effect on your care. It is critical to understand that the study's personnel will not be able to diagnose diseases, administer drugs, or supervise your treatment.
3. It is critical that if you do not comprehend what our team is saying at any time during this process, you raise your hand and let us know.

Our Institutional Review Board has approved this medical research (IRB). These committees, known as ethics committees in other countries, formally examine study proposals in order to ensure participants' safety and well-being in accordance with federal human subject rules and ethical standards.

Why is Rheumatoid Arthritis research being conducted?

Participation in clinical trials has historically been heavily biased toward particular demographic groups. However, research into whether trial attributes influence participation in either favorable or bad ways is scarce. The purpose of this study is to uncover the factors that continually impede patients' capacity to participate in or finish a trial in which they were initially interested. This data will be evaluated via a variety of demographic lenses with the aim of uncovering trends that can help future Rheumatoid Arthritis patients.

What risks should I consider before enrolling in this medical trial?

Throughout the study, there will be frequent online reporting and video conference sessions with participants. Changing treatment regimens always has risks, thus choosing to enroll in a clinical

study in the first place should be carefully examined. This observational research, however, will have NO EFFECT on your treatment course.

One specific risk that exists with a trial is a breach of confidentiality. Breach of confidentiality could mean divulging that individuals reached out staff to be screened and accomplished informed consent forms. The risk of this happening is minimal and the possibility of identity theft is limited by how this data will be handled. The call log, electronic copies of informed consent forms, and the de-identified information are stored and analyzed with strict encryption and password protection in a secured and locked office. There is no way to perform this investigation without the data being used.

What advantages should I consider before enrolling in this medical trial?

This medical research's findings may enhance participation rates and patient diversity in future clinical trials aimed at enrolling rheumatoid arthritis patients.

How does this trial compare to other trials for Rheumatoid Arthritis?

Many of the other clinical trials available for patients with conditions are interventional clinical studies, which require patients to engage in a specified course of therapy. This is an observational clinical experiment, and as such, no therapy will be imposed or offered.

Our team is not intimately familiar with all of the available rheumatoid arthritis clinical trials. If you're interested in learning more, you may look for Rheumatoid Arthritis trials on clinicaltrials.gov or additional rheumatoid arthritis clinical trials on Power's participant reference site.

What is expected of me as a Rheumatoid Arthritis patient?

This trial will consist of bi-weekly surveys that will take around 30 minutes to complete. Quarterly check-in calls will be scheduled for the length of any clinical trial(s) you are engaged in outside of this observational study.

While enrollment in a distinct interventional clinical trial is required for participation, the precise logistics of that trial — including therapy and technique — are completely independent of this investigation and will not be changed in any way. If you have any queries concerning the interventional clinical studies in which you are enrolled, please contact your care team.

Where can I find out more about clinical trial representation?

A few research on clinical trial participation rates have been done. Some examples are shown below:

Gray, Darrell M., Timiya S. Nolan, John Gregory, and Joshua J. Joseph. "Diversity in clinical trials: an opportunity and imperative for community engagement." *The Lancet Gastroenterology & Hepatology* 6, no. 8 (2021): 605-607.

Woodcock, Janet, Richardae Araojo, Twyla Thompson, and Gary A. Puckrein. "Integrating Research into Community Practice—Toward Increased Diversity in Clinical Trials." New England Journal of Medicine 385, no. 15 (2021): 1351-1353.

Stronks, Karien, Nicolien F. Wieringa, and Anita Hardon. "Confronting diversity in the production of clinical evidence goes beyond merely including under-represented groups in clinical trials." *Trials* 14, no. 1 (2013): 1-6.

Participant Statement

I have read and had the above material verbally given to me, and all of my questions have been satisfactorily answered. I realize that my participation in the study is entirely voluntary and that I may withdraw at any moment. My legal rights are not waived by signing this form. I understand that I will be given a copy of this consent. I accept to participate in this research study by signing below.

_____

Printed name of Participant

_____

Participant Signature

_____

Date

Statement of Person Conducting Informed Consent Discussion

I have reviewed the material in this paper with the participant, and I believe the person understands the risks, benefits, alternatives, and procedures associated with this research project.

_____

Printed name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date