

IIR 20-162

**Implementation of Shared Decision Making in Rheumatoid Arthritis: A Stepped Wedge, Cluster-randomized Trial (RAiSeD Study)**

PI: Jennifer Barton, MD MCR

NCT ID: 05530694

CIRB Initial Approval Date: 10/16/2021

Local R&D Committee Approval Date: 11/4/2021

Version: 4/10/2024

# Participant Information Sheet



**HSR&D project #IIR 20-162, "Implementation of Shared Decision Making in Rheumatoid Arthritis: A Stepped Wedge, Cluster-randomized Trial"**

**Funding Agency: VA HSR&D**

**Principal Investigator: Jennifer L. Barton, MD MCR**

**Local Site Investigator:**

You are being asked to participate in a research study conducted by Jennifer L. Barton, MD MCR. We're conducting a study to evaluate how persons with rheumatoid arthritis and their rheumatology clinician make decisions about treatment. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

## **WHY IS THIS STUDY BEING DONE?**

In shared decision making, patients and clinicians work together to identify how to best address the patient's situation. Shared decision making can improve patient knowledge and engagement, and is acknowledged by VA as an evidenced-based practice. This study aims to effectively promote shared decision making between patients and clinicians.

## **WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?**

If you agree to participate, you will be asked to complete a brief survey about your communication with your rheumatologist after the visit. The survey is no more than 3 pages in length, and should take less than 5 minutes to complete. Some participants may be asked to complete a longer survey. This survey will take 10-15 minutes to complete and will be administered at two additional time points: 6 months and 12 months from the initial survey around the time of your regular follow-up appointments.

Additionally, you may be given material to review before your visit with your Rheumatologist, that includes a medication summary guide on rheumatoid arthritis medications and a list of three questions you may ask during your visit. These materials may be in the form of brochures, refrigerator magnets, or postcards.

You may also be asked to have your visit with your rheumatologist audio recorded. A research staff member will place an audiorecording device in the clinic room to record the visit. Recordings will not be disclosed outside the VA. The recordings will be reviewed by trained

study staff and scored for a measure of communication. The audio tapes will not be disclosed to anyone outside the research team or the VA. Current VA regulations require us to keep audio tapes indefinitely. Research records will be retained in accordance with disposition instructions that are approved by the National Archives and Records Administration (NARA) and published in Veterans Health Administration Records Control schedule 10-1. If you choose not to participate in the audiorecording of the clinic visit, you can still participate in the survey part of the study.

### **ARE THERE ANY RISKS OR DISCOMFORTS?**

Any risks from survey and administrative data collection would be due to possible breaches of privacy and confidentiality. It is possible that if a person obtained data this could result in harm to you, with legal, financial, or emotional implications. We will take all possible measures to protect the security and integrity of protected health information. Protected health information will not be disclosed to non-research personnel. We will analyze and report all participant data in aggregate form only, and no protected health information will be reported for any individual.

Your decision to participate or not participate is confidential and you may withdraw from the study at any time.

### **ARE THERE ANY BENEFITS?**

There are no known direct benefits for participating in this study. The proposed study has the potential to improve future patient care experiences.

### **WHO WILL SEE MY INFORMATION?**

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

### **WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?**

You will not receive payment for completion of the brief survey, or for allowing us to audio record your visit. However, if you are asked to complete the longer survey, you will receive \$20. After completion of the two, longer follow-up surveys (6 months and 12 months later) you will receive an additional \$20 for each (3 time points – total of up to \$60). You will receive compensation even if you choose to stop the survey early.

## WHO CAN I TALK TO ABOUT THE STUDY?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.

- **Jennifer L. Barton, MD, MCR**, Jennifer.Barton1@va.gov, 503-220-8262 x54785
  - VA Portland Health Care System, Principal Investigator, Staff Rheumatologist
- **Benjamin Morasco, PhD**, Benjamin.Morasco@va.gov, 503-220-8262 x57625
  - VA Portland Health Care System, Local Site Co-Investigator, Clinical Psychologist
- **Alexandra Bennett, BS**, Alexandra.Bennett@va.gov, 503-220-8262 x52472
  - VA Portland Health Care System, Study Coordinator, Project Manager

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# Clinician Information Sheet



**HSR&D project #IIR 20-162, "Implementation of Shared Decision Making in Rheumatoid Arthritis: A Stepped Wedge, Cluster-randomized Trial"**

**Funding Agency: VA HSR&D**

**Principal Investigator: Jennifer L. Barton, MD MCR**

**Local Site Investigator: \_\_\_\_\_**

You are being asked to participate in a research study conducted by Jennifer L. Barton, MD MCR. We're conducting a study to evaluate how persons with rheumatoid arthritis and their clinicians share decisions for treatment. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

## **WHY IS THIS STUDY BEING DONE?**

In shared decision making, patients and clinicians work together to identify how to best address the patient's situation. Shared decision making can improve patient knowledge and engagement, may help reduce disparities, and is acknowledged by VA as an evidenced-based practice. This study aims to evaluate the impact of shared decision making interventions on the care and experience of patients and clinicians.

## **WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?**

You may participate in several parts of this study. Some people may participate in only one part. You will receive a one-hour communication training whether or not you agree to be in this study. All rheumatology clinicians (fellows and attendings and advanced practice partners) will attend a communication training at each site as part of the usual rheumatology didactic program. Training will be included in the annual rheumatology didactic program. As part of the study you will be provided with materials and tools to support engagement in decision making (point of care decision aid, RA Choice) to be used during usual clinic visits.

You will also be asked for permission to audio record your clinical encounter for a subset of routine clinic visits during the study period. Recordings will not be disclosed outside the VA. The recordings will be reviewed by trained study staff and scored for a measure of communication. The audio tapes will not be disclosed to anyone outside the research team or the VA. Current VA regulations require us to keep audio tapes indefinitely. Research records will be retained in accordance with disposition instructions that are approved by the National Archives and

Records Administration (NARA) and published in Veterans Health Administration Records Control schedule 10-1.

Some professional participants will be asked to participate in two semi-structured interviews lasting up to 60 minutes in length at two different time points, in which an interview guide will be used to explore attitudes toward shared decision making, and structural and organizational barriers and facilitators to implementation of shared decision making. Clinician participants will be interviewed for up to one hour at a time that is convenient and that does not interfere with their official hours of duty. These sessions will also be audio recorded, and transcribed, and qualitatively analyzed to identify themes related to shared decision making. Anything that might identify you will be deleted from the transcript. The audio tapes will not be disclosed to anyone outside the research team or the VA. Current VA regulations require us to keep audio tapes indefinitely. Research records will be retained in accordance with disposition instructions that are approved by the National Archives and Records Administration (NARA) and published in Veterans Health Administration Records Control schedule 10-1. If you choose to participate you can elect to participate in one part of the study (e.g., elect to have your clinical encounters recorded but elect not to be interviewed).

Additionally, any day-to-day activity and interaction you have with clinic staff during the study period may be observed by research staff and documented in field notes.

#### **ARE THERE ANY RISKS OR DISCOMFORTS?**

Semi-structured interviews by their nature may impart a risk to participant privacy. You may find certain questions personal. You may refuse to answer any of the questions. Economic risks will be minimized by scheduling interviews around work schedules, keeping length of time to complete, schedule, and interview to a minimum. We will design our interview guide to keep simplicity and brevity in mind to reduce burden and economic risk. Your decision to participate or not participate is confidential; you may skip questions that you do not feel comfortable answering and may withdraw from the study at any time. The section chief will not know whether you agreed or did not agree to participate and, if you do participate, any data collected will not be shared with your section chief in a manner that would identify you.

Any risks of participating would be possible breaches of privacy and confidentiality. It is possible that if a person obtained our data this could result in harm to research participants, with legal, financial, or emotional implications for the patients so harmed. We will take all possible measures to protect the security and integrity of protected health information.

#### **ARE THERE ANY BENEFITS?**

There are no known direct benefits to individuals for participating in this study. However, by participating in the study you may help us learn how to benefit patients in the future.

## WHO WILL SEE MY INFORMATION?

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

## WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

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  - Portland VA Medical Center VA Portland Health Care System, Research Assistant, Project Manager