



## CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

**Site Principal Investigator:** Sobia Hassan, MD  
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312-563-2800

**Protocol Title:** Optimizing After Visit Instructions in an Outpatient Academic Rheumatology Clinic: A Prospective Randomized Open Label Trial  
**Sponsor:** Rush University Medical Center Rheumatology Department

**Name of Participant:** \_\_\_\_\_

### **Key Information:**

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study later, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to examine the Rheumatology clinic after visit practices (the information or instructions provided by your physician after a clinic visit) and determine if differences in these practices affect patient satisfaction, impact patient understanding about their disease, and possibly affect the course of their disease.

If you agree to participate in this study, your participation may last up to three (3) weeks and you will be asked to complete two (2) study visits, once during your regularly scheduled appointment and another telephone study visit.

During the first visit, which will be in person, you will be asked to complete a health literacy survey (this tests how well you identify medical terms) before your visit as well as complete a satisfaction survey after the visit. Then 1-2 weeks after your in-person visit, you will be

contacted by telephone to answer questions about your visit.

If you agree to be in this study, you will be asked to participate in the following activities:

Before you begin the study:

- You will sign this consent form agreeing to participate in the study. Then, you will be assigned by chance to one of three study groups:
  - The **Control Group**
  - The **After Visit Instructions (AVI) Group**, or
  - The **After Visit Instructions (AVI) with a “teach back” Group**. The specific activities of each study group are explained in the next section.

During the study:

- First, you will complete a health literacy form which will test your ability to identify words commonly used in a rheumatology clinic. This will occur before your normal clinic visit and may take around 5 minutes to complete.
- Then you will see your provider for your normal visit.
  - If you are in the **Control Group** you will complete your usual clinic visit from the same as you would your prior clinic visits.
  - If you are in the **After Visit Instructions Group**, you will receive personalized AVI from the provider outlining changes to your care. This will take an extra 2 minutes for the provider to complete.
  - If you are in the after visit instructions with “teach back” group you will be asked to describe in your own words changes that were made during your visit. This will take an additional 1 minute to complete.
- Finally, you will complete a satisfaction survey after your clinic visit that will ask about how well the provider performed during your visit and your satisfaction with the after visit process. This will take about 3 minutes to complete after your visit.

Follow-up Period

- You will be contacted by phone 1-2 weeks after the visit to answer specific questions based on your appointment visit and after visit processes. This will take about 10 minutes to complete.
- After the follow-up telephone call is completed, we will collect basic baseline data a your electronic medical record including gender, date of birth, ethnicity and race. We will also collect personal health information including the disease for which you see the rheumatologist, medications, and information from forms you fill out prior to every visit that tell us about your disease activity.

This study will obtain medical information from the electronic medical record to be used in our study. For more detailed information please see the section titled “What about confidentiality of your medical information?” below.

There are risks to you for participating in this study. In this study, there is a risk of loss of privacy if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. This study will also

add time to your overall clinic visit however we only expect a maximum additional time of 15 minutes to the entire visit. There are no other expected risks at this time. For a detailed description of risks you should know about, please see the “*What are the risks and discomforts of participating in this study?*” section of this consent form.

You may benefit from the enhanced after visit practices noted in this study. These enhanced after visit processes include standardized after visit instruction templates and having the patient repeat back to the provider all the changes made during the visit (teach back method). Emergency room studies with standardized after visit instructions have shown improvement in general disease and management comprehension in patients. Studies in rheumatology clinics have shown higher percentage of patients taking their medications with the teach back method. We expect all patients in the both intervention groups (after visit instructions only and after visit instructions with teach back) to benefit from this study. However, because individuals respond differently to interventions, no one can know in advance if it will be helpful for you.

If you are assigned to the control group (no after visit enhancement), you are not expected to get any benefits from participating in this study.

This is not a treatment study. Your only other option to participating in this study is not to participate.

**Detailed Information:** Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

**Why are you being invited to participate in this study?**

You are being asked to participate in this study because you are a patient of the Rush University Medical Center Rheumatology Clinic.

**How many participants will take part in this study?**

Approximately 301 participants are expected to take part in this study.

**Will your information be used for research in the future?**

Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

**Will you be contacted about participating in future research?**

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

\_\_\_\_\_ Yes, I agree to be contacted about future research.  
Initials                      Date

\_\_\_\_\_ No, I do NOT agree to be contacted about future research.

Initials

Date

**What if there is new information that may affect your decision to participate in this study?**

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

**Will you receive your individual results from the study?**

Generally, activities performed for research purposes are not meant to provide clinical information. We may learn things about you from this study which could be important to your health or treatment. However, we will not share these results with you because there will be no results from the study that are thought to directly harm the participants.

**Can you leave or be removed from this study?**

You have the right to leave a study at any time without penalty. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

**What about confidentiality of your medical information?**

This authorization is voluntary. Rush University Medical Center and its affiliates (“Rush”) will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Hassan, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Hassan and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained because of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Basic demographics (age, sex, race), new patients versus follow-up visit, MD-HAQ scores (clinic surveys patients complete at every visit), main diagnosis for which you see the rheumatologist, medications, barriers to learning, and patient preferences for learning.
- Name, phone number, date of birth, and date of clinical visit.

Dr. Hassan and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Hassan is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Hassan at 1611 W Harrison Street, Suite 510, Chicago, IL, 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Data that is obtained for this study will be coded when stored for analysis. This data will be held under password locked computers that can only be accessed by persons who have approval for access via the IRB. Those that have access to the coded data will require a key to interpret the data. All data will be deleted at the completion of the study.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

### **What are the costs to participate in this study?**

There are no costs to you for participating in this research.

**Will you be paid for your participation in this study?**

You will not be paid for being in this study.

**What other information should you know about?**

Your health care provider is an investigator on this research study, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this study. You are not obligated to participate in any research study offered by your clinician. The decision to not participate will not affect your clinical care now or in the future.

**Who can you contact for more information about this study?**

Questions are encouraged. If you have further questions about this study, you may call Dr. Dijo Joseph and Dr. Sobia Hassan at 312-563-2800 or email him at [dijo\\_e\\_joseph@rush.edu](mailto:dijo_e_joseph@rush.edu).

**Who can you contact if you have concerns about your rights as a study participant?**

Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

**What are your rights as a study participant?**

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits, or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Hassan in writing at the address on the first page. Dr. Hassan may still use your information that was collected prior to your written notice.

**SIGNATURE BY THE PARTICIPANT**

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

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Name of Participant

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Signature of Participant

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Date of Signature

**SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:**

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

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Signature of Individual Obtaining Consent

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Date of Signature