Consent to Act as a Participant in a Research Study

Study Title: Study: A Pilot Study to Assess Feasibility and Acceptability of MyVoice, a Family Planning Decision Aid for Women with Rheumatic Diseases

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This research study is being conducted by University of Pittsburgh Division of Rheumatology and is funded by a grant from the National Institutes of Health. The purpose of this research study is to explore whether an Internet-based tool called MyVoice or a pamphlet from the American College of Rheumatology helps women with autoimmune diseases to get the information and support they need to make informed decisions about if and when to have a child. You are being invited to participate in this study because you have been diagnosed with one of the follow: rheumatoid arthritis (RA), systemic sclerosis (SSc), myositis, and systemic lupus erythematosus (SLE) and are of reproductive age. You will be one of approximately 50 research participants in this study.

For this study we will ask you to complete surveys and complete either the Internet-based tool, or read a pamphlet from the American College of Rheumatology. The surveys will be sent to your cell phone number or email via a link. These surveys will take 30-40 minutes to complete. Then, you will receive either the web tool MyVoice to complete electronically, or you will receive the pamphlet (either in paper or electronically) to read. This step may take you 20 minutes to do before your clinic appointment.

We are selecting people to receive either MyVoice or the pamphlet randomly (like flipping a coin), so we cannot select what option you receive.

After your appointment with your rheumatologist, you will be asked to complete additional surveys electronically, which will take about 15-20 minutes to complete. You will also have a 20-minute interview with the research coordinator about your experiences with your rheumatology visit and with the tool. This interview may happen either in person or over the phone.

Three months after the study visit, we will contact you to complete a follow-up survey and interview about whether or not the tool has affected any of your reproductive health decisions or plans. This will take approximately 30-40 minutes to complete and will be done via phone and an emailed survey link.

Altogether, we expect that you will spend up to THREE hours participating in the study. Some people may spend a little more time, and some people may spend a little less time completing the study. This does not include the time for your visit with your rheumatologist.

We are also requesting your authorization or permission to review your medical records. After your clinic visit, a study coordinator will look in your electronic health record to see if your rheumatologist ordered anything related to family planning care, such as a prenatal vitamin or emergency contraception.. We will obtain the following information: orders for pregnancy tests, emergency contraception, non-emergency contraception, referrals for obstetrics-gynecology or maternal-fetal medicine, referrals for PCP consultations for family planning, changes in medications and documentation of pregnancy. This review will occur immediately after your visit and again around 90 days afterward. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time.

You will be compensated $100 for completing this study. You will receive $10 for completing the baseline survey, $15 for completing the exit survey, $30 for completing the exit interview, $15 for completing the three month follow-up survey, and $30 for completing the three month follow-up interview.

Payment will be issued in the form of a debit card which will be given to you at your study visit or mailed to you if you are participating via telehealth. In order to issue you a debit card we will need to collect your social security number and mailing address. Social security numbers will be entered electronically into a very secure computer system that is available to research study staff only. It will be used for no other purpose than to track participant payments. Members of the research team will not keep this information in their research files. Should you participate in any other research studies throughout the year and receive total monetary compensation that exceeds $600, an Internal Revenue Service (IRS) 1099 form will be sent to you.

There are some risks associated with participation in this research study. You may feel a little uncomfortable while answering questions about yourself and your reproductive experiences and decisions. You can refuse to answer any questions you choose. There are no direct benefits to participating in this research study; however, the information that you provide will help us develop tools to help other women like you to make well-informed reproductive decisions.

Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there are minimal risks to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. All of your study materials (i.e., interview data) will be identified by a unique ID number. All paper records containing any information that might identify you, like your name, will be kept in a separate place from records identified by your study ID. Your social security number will be used for participant payment processing purposes only. All study documents will either be stored in locked filing cabinets in locked offices or will be stored on a University of Pittsburgh-security approved computer server. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of the study. Please be aware, if the researchers learn that you or someone with whom you are involved is in serious danger of harm, they will need to inform the appropriate agencies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Your research data may be shared with investigators conducting similar research; however, this information will be shared in a de-identified manner without any information that could identify you as the provider of the information.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the University of Pittsburgh Research Conduct and Compliance Office, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

Please know that your participation in this study is voluntary as you have the choice to not participate in this research study. You can withdraw from this study at any time. Your consent to the University of Pittsburgh's request to use audio recording is also voluntary and you may rescind your consent at any time. You can also withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. To formally withdraw from this study, you should provide a written and dated notice of this decision to the principal investigator. Any information obtained from you up to the point of withdraw will continue to be used by the research team. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh. Please also know that your rheumatologist and other physicians will not be informed that you are participating in this study, and we will not share your results with them.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____

Print Participant Name

_____ _____

Participant Signature Date

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date