Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Medication Adherence Patterns in Rheumatic Diseases: A Behavioral Trial

"Using cues and rewards to improve medication adherence for patients with arthritis and rheumatic disease" (Phase 2: Trial Phase)

Principal Investigator: Candace Feldman, MD, ScD

Site Principal Investigator: N/A

Description of Subject Population: English-speaking adults with rheumatoid arthritis, lupus, and/or gout taking one or more oral medications for their disease

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study, we want to learn more about what helps people take their medication. The goal is to find ways to help patients take their medications better.

How long will you take part in this research study?

If you decide to join this research study, it will take you about **6 months** to complete the study, during which you will be asked to use an electronic pill bottle and may receive text messages. During this time, we will ask you to have **3** brief virtual visits with Brigham and Women's Hospital study staff.

What will happen if you take part in this research study?

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

1) You will be asked to use between one to three electronic pill bottles for you to put your daily diabetes medication in. We ask that you use the Pillsy electronic pill bottle for 6 months so we can observe how you take your medication.
2) You may be the recipient of the following strategies: participating in a goal-setting exercise to help you remember to take your medication, receiving daily texts reminding you to take your medication, and choosing a charity to which a donation will be made by the BWH every time you take your medication.
3) You will complete a follow-up survey regarding your medication use.

Why might you choose to take part in this study?

You will not benefit from taking part in this research study beyond potentially improving how often you take your medication as prescribed. Others with rheumatologic conditions may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. Important risks and possible discomforts to know about include breach of confidentiality. A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?". Other things to consider are your willingness to use an electronic pill bottle for 6 months and receive reminders about your medication and the time associated with taking the surveys.

What other treatments or procedures are available for your condition?

Your rheumatologist or primary care physician is currently prescribing medication to treat your rheumatic condition. You should continue to take these medications and do not have to participate in this study to be treated.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Candace Feldman, MD, ScD is the person in charge of this research study. You can call him/her at **617-732-5325 M-F 9-5**. You can also call **Niteesh Choudhry, MD, PhD, Co-Investigator** at **617- 278-0930 M-F 9-5** or **Constance Fontanet, Research Assistant,** at **857-307-3805 M-F 9-5** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Constance Fontanet** at **857-307-3805 M-F 9-5.**

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

We are conducting this research study to find out what helps people take their medication. The goal is to find ways to help patients take their medications better. We are asking you to use an electronic pill bottle for 6 months and be willing to be the recipient of the following strategies: participating in a goal-setting exercise to help you remember to take your medication, receiving daily texts reminding you to take your medication, and choosing a charity to which a donation will be made by the BWH every time you take your medication.

Who will take part in this research?

We are asking you to take part in this research study because you are at least 18 years of age and have experience taking a medication for a rheumatic condition (rheumatoid arthritis, lupus, and/or gout). We expect that up to 60 patients will participate in this study at Brigham and Women's Hospital. The National Institute on Aging is paying for this research to be done.

What will happen in this research study?

If you decide to join this research study, the following things will happen: you will be asked to use an electronic pill bottle and potentially participate in several activities.

1) Using the electronic pill bottle: We will ask you to complete a brief questionnaire. Then we will give you between one to three electronic pill bottles for you to put your daily rheumatology medication in. The study staff member will explain to you which medications to put in the bottles and give you instructions on how to use the bottles. We ask that you use the Pillsy electronic pill bottle for 6 months so we can observe how you take your medication. Every time you open your medication bottle, the time and date of opening will be transmitted to the Pillsy platform through a smartphone application (app) that we will help you download on your phone. Pillsy will be able to access the dates and times you open the pill bottles and your study-specific ID number. They will not have access to your telephone number or other personal identifying information.
2) You may be asked to help think about strategies that can be used to help you remember to take your medications.
3) Text messages: If you enroll in this study, we may send you text messages.
4) Charitable donation: If you enroll in this study, a donation may be made to a charity depending on which group you are assigned to.
5) We expect each study visit to take 30-45 minutes of time. We will otherwise not contact you in any way.

Inclusion in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. If your rheumatologist or primary care physician feels that this information was an important factor in his/her decision-making, he/she may choose to enter data learned from this study into your electronic medical record to document part of the routine clinical decision-making process. You will also be given feedback at the end of the study about the way you take your medications and you can choose whether or not you wish to share this with your rheumatologist or primary care physician.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

At the end of the study after completing the follow-up questionnaire, we will give you a printout with a description of the way you take your medications. You can choose whether or not you want to share this with your rheumatologist or primary care physician. We are also happy to share the final results of the study once completed if you are interested. We will also post these results online at clinicaltrials.gov.

What are the risks and possible discomforts from being in this research study?

We expect there to be minimal risks to participating in this study. During the 1st part of the study, you will just be asked to use a new container for your medication, the Pillsy electronic pill bottle. This pill bottle is commercially available and will record the date and time at which you open the bottle to take your medication, associated with your de-identified study-specific ID number, on their servers.

Agreeing to use the Pillsy electronic pill bottle for this study means that you agree to the Pillsy Terms of Use and Privacy Policy. Pillsy should not be used in place of medical advice from your doctor and is not liable for any decisions or actions taken regarding your medication use. If you register on the website, subscribe to a newsletter, or enter information into the application, any information you provide to Pillsy may be used for improved customer service. <u>However, none of these actions are required in order to participate in this study.</u>

If you currently use a pillbox for your medications, there is a small risk that using electronic pill bottles during this study could change your daily medication-taking routine.

You may also receive up to daily text messages to remind you to take your medication. We will use an online platform to send you text messages. The text messaging platform will have access to your telephone number and the content of the text messages but will not have access to other identifiable information such as your full name, date of birth, or address.

Text messages by mobile/cell phones are a common form of communication. The research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare (Mass General Brigham) are not responsible for any interception of messages sent through unencrypted text message communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts
- Text messages will not be routinely monitored by a live individual, but some text messages you receive may ask you to text a response back. We encourage you to send a response if prompted, but it is your decision and will not affect your study participation or outcomes. If you choose to send a response, you may receive an automatic message stating that this text messaging system is not monitored by a live individual, and in case of the need for urgent medical attention, you should call 911, go to your nearest emergency department, or call the 24-hour nurse helpline for you BWH rheumatology or primary care practice.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop".
- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

There is a risk that the programs' servers could be compromised, either by hackers or other computer failures, and this data made public, resulting in the unwanted release of health information. Risks of this sort will be minimized by only uploading de-identified data to the Pillsy server and only uploading your phone number to the text messaging platform, so that these external platforms do now have access to information such as your name or location.

You may withdraw from this study at any time and this will in no way affect the care you receive at Brigham and Women's Hospital.

What are the possible benefits from being in this research study?

You can keep the electronic pill bottles at the end of the study. There may otherwise not be any direct benefit from taking part in this study. We hope others with rheumatic conditions will benefit in the future from this research.

What other treatments or procedures are available for your condition?

Your physician is currently prescribing medication to treat your rheumatic condition. You should continue to take these medications and do not have to participate in this study to be treated.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

Participants will receive a $50 Amazon gift card at the completion of the study. In order to process the honorarium, we will need to collect your social security number. This information will be stored securely and destroyed when the research is completed. You can also keep the electronic pill bottles after the study is completed.

What will you have to pay for if you take part in this research study?

We do not anticipate any additional costs to you from participation in this research study. Study funds will pay for certain study-related items and services. You will be responsible for payment of any deductibles and co-payments required by your insurer for any routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: V2 March 23rd, 2021