TITLE: Real-time Symptom Monitoring Using ePROs to Prevent Adverse Events During Care Transitions

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Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: February 2022

Subject Identification

Protocol Title: Real-time symptom monitoring using ePROs to prevent adverse events during care transitions

Principal Investigator: Anuj Dalal

Site Principal Investigator:

Description of Subject Population: Adult inpatients, 18 years or older

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.

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.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead, we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you have two or more chronic conditions while being hospitalized. We are doing this research to better understand if using a web application to report symptoms after you leave the hospital will help prevent any unwanted side effects. If you agree, you will be assigned to the intervention group or usual care group. If assigned to the intervention group, we will show you how to use a web application ("web app") which you can access through Patient Gateway and enables you to

monitor your symptoms after you leave the hospital. Thirty-days after being discharged, we will contact you using secure email or text message to participate in a follow-up survey and a follow-up phone call interview about any healthcare visits any new or worsening symptoms that you may have experienced after leaving the hospital, and usability of the web application. We will also review your health information recorded in the electronic health record to better understand if any side effects occurred after you left the hospital. You will be in the study for up to 30 days after you are discharged from the hospital if you decide to stay for the whole study.

There are no known risks associated with participating in this research. There is a theoretical risk of breach of confidentiality or that the information you provide to us could become known to unauthorized persons. We will take all steps necessary to protect your information to minimize this risk.

You will be paid $40 for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

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

Dr. Anuj K Dalal, MD is the person in charge of this research study. You can call him at [redacted] **or email at** [redacted]. You can also **email Savanna Plombon, the research project coordinator, at** [redacted] with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. 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

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

Why is this research study being done?

We are doing this research to better understand if using a web application to report symptoms after you leave the hospital will help prevent any unwanted side effects among patients with two or more chronic conditions.

Who will take part in this research?

We are asking you to take part in this research study because you have two or more chronic conditions while being hospitalized. About 850 people will take part in this research study. The Agency for Healthcare Research and Quality is paying for this research to be done.

What will happen in this research study?

If you agree to participate, we will assign you by chance to the intervention group of the usual care group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the intervention. You will have a 1 in 2 chance of being assigned to usual care. To participate, you should be willing to be assigned to and participate in either of the two study groups. Your primary care provider will be told that you are participating in the study.

If you are in the "intervention group", you will be given access to the web application through Patient Gateway or a secure web link we will send to you by secure email or by SMS texting with your consent and you will be asked to use it for up to 30 days after you are discharged from the hospital.. The web application will collect general health information using a questionnaire, allow you to view self-management advice specific to your discharge plan, and include self-identified concerns from the discharge preparation checklist that you complete in the hospital. Your clinician may receive a secure email or inbasket message based on responses to the general health information questionnaire if your responses indicate that you may desire to communicate with your clinician. For both

groups, we will ask you to complete several standardized questionnaires about your general health, health literacy, discharge preparedness, and self-management abilities prior to being discharged from the hospital. We will show you how to use the web application.

If you are in the "usual care" group, you will receive the care that patients normally receive. This means your doctors and nurses will look after you as they have always done.

For both groups, upon enrollment, we will ask you to complete several standardized questionnaires about your general health, health literacy, discharge preparedness, and self-management abilities prior to leaving the hospital. A research assistant will administer the questionnaires via tablet or electronically in REDCap, paper or pencil, or verbally or the questionnaires can be self-administered by the patient. When the questionnaires are self-administered by the patient, they collectively take approximately 10-15 minutes to complete. When verbally administered, in total they take approximately 20-25 minutes to complete.

Thirty-days after being discharged, we will contact you by secure email or text message to the email or phone number you provide to participate in a follow-up survey about any symptoms you experience after leaving the hospital. We will also contact you by phone using the phone number you provide to participate in a follow-up phone interview. During the phone call interview we will ask you questions about any healthcare visits ,any new or worsening symptoms that you may have experienced after leaving the hospital, and the usability of the web application. We will also review your health information recorded in the electronic health record to better understand if any side effects occurred after you left the hospital.

We may re-contact you again to participate in an interview to help us assess the impact of the web application.

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

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, medical record number, 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?

You can choose to receive the results of the research study we are doing. We will also publish what we learn in medical journals.

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

There are no known risks associated with participating in this research. There is a theoretical risk of breach of confidentiality or that the information you provide to us could become known to unauthorized persons. We will take all steps necessary to protect your information to minimize this risk.

This 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. You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts. It is your responsibility to update your mobile/cell phone number with this research study in the event of a change. I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

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

You may not directly benefit from participating in this study. If successful, we may better understand how to monitor symptoms and unanticipated events that happen in patients with multiple chronic conditions who have been discharged from the hospital. This may result in

improved quality of life, quicker escalation of worrisome symptoms or potential adverse events, and fewer unnecessary healthcare encounters, after being discharged from the hospital.

Can you still get medical care within Mass General Brigham 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 Mass General Brigham 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?

You will be compensated with a $40 gift card within approximately 6 weeks after you complete the study.

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

You will not have to pay for access to the ePROs web application.

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this 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 Mass General Brigham 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 they may need to do so:

- Mass General Brigham 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 Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham 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:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 study 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 health information to be used and shared as described above.

Subject _____ Date _____

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____	_____	_____
Signature	Date	Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- 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, and my questions have been answered.

Signature of Adult:

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

Adult	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 of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

The consent form was presented orally to the subject in the subject's own language, the subject was given the opportunity to ask questions, and the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____
(fill in above)

Consent Form Version: 11/02/2022