

CARE COORDINATION SMARTPHONE PILOT PARTICIPATION AGREEMENT

TITLE: Evaluate the efficacy of Smartphone App-based communication to track patient recovery at home after discharge from hospital.

SPONSOR: Midas+ Solutions, a Xerox Company, and PARC, a Xerox Company

SITE(S): IU Health Goshen Hospital, 200 High Park Ave., Goshen, IN 46526

PILOT PROGRAM-RELATED CONTACT NAMES, ADDRESSES, and PHONE NUMBER(S):

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INVITATION TO PARTICIPATE IN CARE COORDINATION PILOT:

You are invited to participate in a pilot program to evaluate the efficacy of using Smartphone App-based communication to track patient recovery at home after discharge from hospital.

The purpose of this agreement form is to help you decide if you want to be in the pilot program. You should not join this pilot program until all of your questions are answered.

Things to know before deciding to take part in a pilot program:

- The main goal of a pilot program is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the pilot program will not cause you to lose any medical benefits. Your doctor will continue to treat you regardless of whether you decide to (or decide not to) take part in this pilot.

If you take part in this pilot, you will be given a copy of this signed and dated agreement form.

PURPOSE OF CARE COORDINATION SMARTPHONE PILOT:

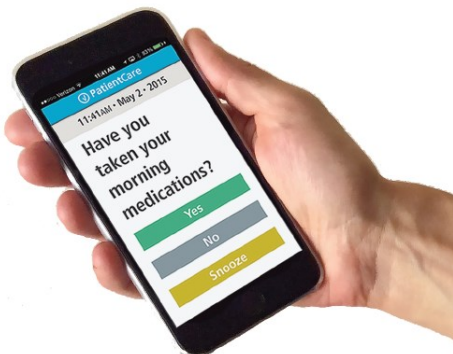
- This pilot program is being done to evaluate the effectiveness of using Smartphone App-based communication between patients and the healthcare coordination team at the hospital, to track the recovery of patients after discharge from the hospital.
- Up to 200 patients who own and regularly use a Smartphone will be enrolled in the pilot out of which up to 100 patients chosen at random will be provided access to a smartphone app. The App will be used to pose questions to patients related to their general health and respective hospital discharge instructions for a period of 30 days after time of discharge from the hospital. The questions posed may be in a multiple-choice format or may require type-in responses (e.g., entering your weight, etc.).
- The patients given access to the Smartphone App will have questions posed to them every day through the App which they need to respond to and, their responses will be recorded and relayed to the respective healthcare coordination team at the hospital . These responses will be used to track the patient's recovery process, address any questions or concerns and contact the patient via phone if necessary.
- At the end of the pilot period (30 days after discharge), the Smartphone Pilot team and hospital staff's access to the patient's Smartphone-App will be disabled and questions will no longer be posed to the patient through the App.

DESCRIPTION OF SUBJECT INVOLVEMENT (PROCEDURES)

- **Smartphone App:** As determined by the pilot team, some of the subjects enrolled in the program will be chosen randomly to be given access to the 'Patient Engagement' Smartphone App. The remaining subjects will NOT be provided access to the 'Patient Engagement' Smartphone App.

Once given access, the patient will download the 'Patient Engagement' App from the Google® Play or Apple® iOS app store in to their personal Smartphone running either an Android or iOS operating system respectively, upon accepting the necessary terms and conditions of use by the respective Smartphone App store.

- **Training on use of App:** If you are given access to and download the 'Patient Engagement' App in to your Smartphone you will be taught how to use it by the pilot personnel:
 - The pilot program personnel will help you register by entering a unique enrollment ID in your Smartphone App, which will serve as your subject ID during the pilot. The subject ID will serve as the only patient identifiable information used by the App.
 - The pilot program personnel will demonstrate the use of the App by posing sample questions and guiding you to answer them using your Smartphone interface.



- On the left is a view of an example of the ‘Patient Engagement’ Smartphone App interface with a sample multiple-choice question posed requiring you to choose either a ‘Yes’ or ‘No’ response.
 - When a question is posed to you, your Smartphone will vibrate and provide audio and/or visual notification of a pending question which will require your response in the App.
 - You will be asked to respond to up to 5 sample questions through the Smartphone App, with the help of the pilot personnel in order to complete the training process.
 - The pilot personnel will answer any questions you may have regarding the use of the Smartphone App.
 - At the end of the training, a pilot brochure / quick-reference guide will be provided for your reference to take home after discharge from the hospital.
- **Periodic questions posed to patients via App:** If you are provided access to the Smartphone App, for a period of 30 days after time of discharge from the hospital, you will be posed questions on it every day requiring not more than a total of 15 minutes per day to respond and your responses will be recorded. Your responses to questions will be regularly reviewed and/or analyzed, and used to help the hospital staff to track your recovery process. If necessary, the hospital staff may contact you directly to provide feedback and/or address any questions or concerns you may have, as part of your usual medical care.
- **End of Pilot:** At the end of the pilot program period (30 days after discharge), the pilot team and hospital staff’s access to your Smartphone-App will be disabled and questions will no longer be posed to you through the App. At this point, you will be free to delete the Smartphone App from your Smartphone.

RISKS AND DISCOMFORTS

The Smartphone App is NOT an alternative to regular medical care and NOT a direct means of communication with your doctor. In the event of an emergency or if you would like to speak to your doctor or another member of your care team, please follow the discharge instructions provided by the hospital.

The pilot program team has taken steps to minimize your risks in taking part in this pilot. Even so, you may still have problems or side effects related to your participation in this pilot, even when the pilot program team are careful to avoid them. These risks may include the following:

- Time burden in answering questions on Smartphone App: Pilot program team members have mitigated this risk by ensuring that a limited number of questions are posed to the patient every day requiring a maximum of 15 minutes of your time per day.
- Confidentiality of your answers to questions posed on Smartphone App: Pilot program team members have mitigated this risk by ensuring that your responses are de-identified and relayed only to the concerned hospital staff tracking your post-discharge recovery via a HIPAA-compliant communication channel.

BENEFITS

It cannot be promised that you will receive any medical benefits from participating in this pilot program. Although you may not directly benefit from being in this pilot, others may benefit in the future as follows:

- The pilot may help in developing a good communication system between the patient and hospital staff, so that patients have an improved recovery process post hospital discharge.
- The pilot may help ensure that patients are asked appropriate questions at the right time in order to ensure efficient tracking of patient's recovery process post hospital discharge.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to be in this pilot program. Your decision to join or not to join this care coordination pilot program will not cause you to lose any medical benefits. Regardless of whether (or not) you decide take part in this pilot, your doctor will continue to treat you.

COSTS

The participants will incur no additional expenses as a result of participation. You or your insurance company may be billed for any standard medical care given during this pilot program. By signing this agreement form, you agree that you do not have any rights, either present or future, to any invention, concept, idea, intellectual property, product, method, or device that is conceived, reduced to practice, created, developed, derived from, or improved by the pilot or that otherwise results from or is associated with this pilot.

CONFIDENTIALITY

Authorization to release your protected health information

Agreeing to be in this pilot program gives pilot program team members your permission to obtain, use, and share information about you for this pilot, and is required in order for you to take part in the pilot. Your information will only be used for analyzing the results of the pilot. The only information from your health records that will be used for the pilot program is the following:

1. Patient's Name or Initials
2. Patient's age
3. Date & Time of hospital admission
4. Clinical diagnosis for hospital admission
5. Date & Time of hospital discharge
6. Date & Time of re-admission(s) (if any)
7. Clinical diagnosis for hospital re-admission(s) (if any)

We plan to publish the results of this Care Coordination pilot program, but will not include any information that would personally identify you. There are some reasons why people other than the pilot program team members may need to see information you provided as part of the pilot. This includes organizations responsible for making sure the pilot program is done safely and properly, including IU Health Goshen Hospital, Midas+ Solutions, and Palo Alto Research Center (PARC), A Xerox Company.

To keep your information safe, the pilot program team members will store your information on a HIPAA compliant server with adequate data security, and only the team members on the project may have direct access to any information that could identify you. Only derived, unidentifiable information, such as number of patients, average duration of stay of the patients, etc., will be shared beyond the pilot program team members.

The privacy law protects your health information. It requires your permission to allow the pilot program team members to use and share your protected health information with others for research. You will be asked to sign a separate form to let the pilot program team members to use health information for this research.

VOLUNTARY NATURE OF THE PILOT

Participating in this pilot program is completely voluntary. If you take part in this pilot program, you have the right to the information you provide during your participation in the pilot. Even if you decide to participate now, you may change your mind and stop at any time. If you decide to terminate your participation in the pilot, or if you are removed from the pilot by the principal pilot program team member, you may revoke this authorization to obtain your private health information. To end your authorization, you must notify the IU Goshen Hospital point of contact in writing at the address provided on Page 1 of this agreement form. Upon termination of your participation in the pilot program, the pilot program team and hospital staff's access to the 'Patient Engagement' Smartphone-App will be disabled and questions will no longer be posed to you through the App. However, information that has already been collected cannot be removed from the pilot or medical records.

If significant new knowledge is obtained through the course of the pilot which may relate to your willingness to continue participation, you will be informed. You may be asked to sign a new agreement form in that event, and you will be free to decline / terminate your participation from this pilot at that or any other time, if you prefer.

The Care Coordination pilot program personnel may remove you from the pilot at any time, without asking you, if he or she feels it is in your best interest because:

- (1) You fail to follow instructions given by the pilot personnel
or
- (2) The sponsor stops the pilot for any reason.

WHOM TO CALL FOR ANSWERS TO QUESTIONS

You have the right to ask any questions you have about this pilot before you sign. Do not sign this agreement form unless you have had all your questions answered.

If you have any questions about the pilot program or subject rights, please feel free to contact any of the pilot points of contact individuals listed on page 1 of this form.

PARTICIPANT'S ACKNOWLEDGEMENT:

I have read and understand this agreement form. I agree to take part in this pilot program. By signing this form I do not waive my legal rights.

I have received a satisfactory explanation:

- Of the procedures to be followed
- Of the risks and possible benefits
- Of alternative treatments
- About the release of my medical records
- That my doctor may stop the pilot at any time
- That I may stop at any time without penalty or loss of benefits

I will receive a signed copy of this agreement form.

Subject's Name
(Typed or Printed)

Signature

Date

ACKNOWLEDGEMENT OF PERSON OBTAINING AGREEMENT:

I attest to the following: (1) that the requirements of informed agreement for the medical research project described in this form have been satisfied (2) that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate (3) that I have discussed the pilot project with the subject and explained to him or her in non-technical terms all of the information contained in this agreement form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Name of Person Obtaining Agreement
(Typed or Printed)

Signature

Date

CARE COORDINATION SMARTPHONE PILOT PARTICIPATION AGREEMENT

AUTHORIZATION FOR THE USE AND DISCLOSURE OF PRIVATE HEALTH INFORMATION

Name of Pilot:

Evaluate the efficacy of Smartphone App-based communication to track patient recovery at home after discharge from hospital.

Patient's Name:

Use and Disclosure of Your Medical Information

By signing this form, you are authorizing the use and disclosure of your private health information in connection with your participation in this pilot program.

Your information will only be used in accordance with the provisions of this authorization and any other disclosure laws that we may be required to follow.

Do I need to sign this authorization form?

You do not have to sign this agreement form. But if you do not, you will not be able to participate in this pilot program. Signing the form is not a condition for receiving any medical care outside of the pilot.

What Information Will Be Used or Disclosed?

Your information related to this pilot, including, but not limited to, your name and / or initials, age, date & time of hospital admission, clinical diagnosis for hospital admission, date & time of hospital discharge, date & time of re-admission(s) (if any), clinical diagnosis for hospital re-admission(s) (if any), may be used or disclosed in connection with this pilot program.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this pilot program:

- IU Health Goshen Hospital

Who May Receive/Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this

pilot program:

Program Sponsors:

- Midas+ Solutions, A Xerox Company
- Palo Alto Research Center (PARC), A Xerox company

If any information from this pilot is published (e.g., in a research paper or other public forum such as at a research conference), or otherwise made available to anyone beyond the above-listed entities, only de-identified information will be used (e.g., high-level summary such as number of patients in the pilot, size of patient groups with specific reasons for admission or readmission, statistical analyses of the cause of and rates of post-discharge readmission events or follow-up events based on information collected during the pilot etc. Personally identifiable information about you will not be shared in any external publications and will only be available to your care team and those individuals conducting and/or administering this pilot.

Expiration

Your authorization for the use and/or disclosure of your health information will expire January 1, 2025.

When Access to Your Information May Be Limited

You may not be allowed to see or copy certain information in your medical or pilot records collected in connection with your participation in this pilot while the program is still in progress. This information includes, but is not limited to, your responses to questions posed on the Smartphone. However, if it is necessary for your medical care as determined by your physician at IU Health Goshen Hospital, your health information will be provided to you or your physician.

Revocation

If you decide to terminate your participation in the pilot, or if you are removed from the pilot by the principal program team member, you may revoke your authorization to obtain your private health information. To end your authorization, you must notify the IU Health Goshen Hospital point of contact in writing at the address provided on Page 1 of this agreement form. Upon termination of your participation in the pilot, the pilot program team and hospital staff's access to the 'Patient Engagement' Smartphone-App will be disabled and questions will no longer be posed to you through the App. However, information that has already been collected cannot be removed from the pilot or medical records.

The pilot program personnel may remove you from the pilot at any time, without

asking you, if he or she feels it is in your best interest because:

- (1) You fail to follow instructions given by the pilot program personnel
or
- (2) The sponsor stops the pilot for any reason.

Signature

Signature of Pilot Program Participant

Date

Signature of Legally Authorized Representative (if
applicable)

Date

Description of Representative's Authority to Act for
Subject